

EXHIBIT E

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

3 IN RE: ETHICON, INC., Master File No.
4 PELVIC REPAIR SYSTEM PRODUCTS 2:12-MD-02327
5 LIABILITY LITIGATION, MDL No. 2327
/ JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

5 THIS DOCUMENT RELATES TO
6 PLAINTIFFS:

6	Joplin, Deborah Lynn	2:12-cv-00787
	Wheeler, Pamela Gray	2:12-cv-00455
7	Collins, Fran	2:12-cv-00931
	Frye, Jackie	2:12-cv-01004
8	Bennett, Dina Sanders	2:12-cv-00497
	Miracle, Charlene	2:12-cv-00510
9	Adams, Joan	2:12-cv-001203
	Grabowski, Louise	2:12-cv-00683
10	Vignos-Ware, Barbara	2:12-cv-00761
	Harter, Beth	12-cv-00737
11	Scholl, Sheri	12-cv-00738
	Stubblefield, Margaret	12-cv-00842
12	Warmack, Roberta	12-cv-01150
	Smith, Carrie	2:12-cv-00258
13	Thomas (Wyatt), Kimberly	2:12-cv-00499
	Georgilakis, Teresa	2:12-cv-00829
14	Cone, Mary	2:12-cv-00261
	Destefano-Raston, Dina	2:12-cv-01299
15	Hooper, Nancy	2:12-cv-00493
	Lee, Alfreda	2:12-cv-01013
16	Reyes, Jennifer	2:12-cv-00939
	Fisk, Paula	2:12-cv-00848
17	Sikes, Jennifer	2:12-cv-00501
	Swint, Isabel	2:12-cv-00786
18	Teasley, Krystal	2:12-cv-00500
	Thaman(Reeves), Susan	2:12-cv-00279
19	Warlick, Cathy	2:12-cv-00276
	Sheperd, Donna	2:12-cv-00967

20
21 DEPOSITION OF JAIME SEPULVEDA, M.D.

22 Wednesday, March 30, 2016
23 8:12 a.m. - 4:33 p.m.
200 South Biscayne Blvd.
24 Miami Beach, Florida

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1 P R O C E E D I N G S

2 - - -

3 Thereupon:

4 JAIME SEPULVEDA, M.D.,

5 having been first duly sworn, was examined and
6 testified as follows:

7 THE WITNESS: I do.

8 DIRECT EXAMINATION

9 BY MR. DE LA CERDA:

10 Q. Okay. Doctor, could you please state your
11 full name for the record?

12 A. Jaime L. Sepulveda.

13 Q. You're a urogynecologist hired by Johnson &
14 Johnson and Ethicon, Inc. to provide opinions in
15 support of TVT, TVT-O, Gynemesh, Prolift and Prosima;
16 correct?

17 MR. SNELL: Form.

18 A. I have -- I have been subpoenaed to provide
19 expert testimony about these products.

20 Q. (By Mr. De La Cerda) My name is Peter
21 de al Cerda, I'm one of the attorneys who represents
22 the plaintiffs' group.

23 Do you understand who I am and who I
24 represent?

1 A. Yes, I do.

2 Q. A couple of deposition rules. As we begin,
3 first of all, we want to try to let each other finish,
4 so allow my question to get out fully before you begin
5 your answer and then I'll allow your answer to get out
6 fully before I begin my next question. Is that fair?

7 A. Yes.

8 Q. And also when you're responding to
9 questions, please do so verbally as opposed to an
10 "uh-huh" or "uh-uh" or a head nod so it is clear on
11 the record. Okay?

12 A. Yes.

13 Q. Also, if you don't understand my question,
14 please ask me to repeat or rephrase it, otherwise,
15 I'll assume that you understood my question. Is that
16 fair?

17 A. Yes.

18 Q. And, of course, if you need a break at any
19 time, please let me know and we'll take a break. The
20 only thing is if there's a question pending, I ask the
21 question be responded to before we take the break.
22 Okay?

23 A. I -- I understand.

24 Q. All right. This is not the first deposition

1 you've given; correct?

2 A. That's correct.

3 Q. What other depositions have you given?

4 A. I have given depositions on Garcia versus
5 Ethicon.

6 Q. Okay. Anything else?

7 A. Yes, I have given deposition in local cases
8 against a physician.

9 Q. Okay. So any other mesh cases where you've
10 given a deposition other than Garcia?

11 A. Only Garcia.

12 Q. Okay. And then you've also given
13 depositions, I guess, in medical malpractice cases?

14 A. Yes.

15 Q. Okay. How many of those have you given?

16 A. I have given two.

17 Q. Two. And have you acted as a treater or as
18 an expert in those cases?

19 A. One was as a treater and the other one was
20 as an expert.

21 Q. Okay. And when you acted as the expert,
22 were you for the plaintiff or for the defense?

23 A. I was for the defense.

24 Q. And generally speaking, in the case where

1 you were the treater, what type of case was that? I
2 know it's medical malpractice, but what was the
3 subject of that case?

4 A. That -- that was in 1994, a pelvic mass,
5 specifically a sacral mass.

6 Q. Okay. And then how about the one where you
7 acted as the expert for the defense?

8 A. It was a case of urinary incontinence after
9 a vaginal delivery.

10 Q. And do you recall approximately when that
11 one was?

12 A. That may have been three to four years ago.

13 Q. Did either of those cases involve Butler
14 Snow?

15 A. No.

16 Q. Okay. And then in the Garcia versus
17 Ethicon, you acted as an expert on behalf of Johnson &
18 Johnson and Ethicon; correct?

19 A. That's correct.

20 Q. All right. Any other depositions other than the
21 ones you already mentioned?

22 A. No other depositions.

23 Q. Okay. A few questions here. I assume the
24 answers to these are all no, but have you ever had

1 your privileges at a hospital revoked, suspended or
2 limited in any way?

3 A. No.

4 Q. Have you ever personally been sued for
5 medical malpractice?

6 A. Yes.

7 Q. Okay. And what was the subject of that
8 particular case?

9 A. It -- it was, again, a chordoma,
10 c-h-o-r-d-o-m-a, a chordoma, which is a tumor on the
11 sacrum.

12 Q. I see. Okay.

13 A. And the other one was an injury to the
14 ureter during the excision of a 20-centimeter pelvic
15 mass.

16 Q. Okay. So these are two separate cases;
17 correct?

18 A. Yes.

19 Q. In the first case that involved the
20 chordoma, so you were the defendant in that case?

21 A. Yes.

22 Q. And was this the one from 1994?

23 A. Yes.

24 Q. Okay. So you actually gave a deposition in

1 that case; right? Is that right?

2 A. Yes.

3 Q. And in the second case, the injury to ureter
4 with the pelvic mass, did you end up not giving a
5 deposition in that case?

6 A. There was no deposition.

7 Q. Okay. Without revealing -- I know
8 settlements many times can be confidential. Without
9 revealing any confidentiality, can you tell us
10 anything about the resolution of those two cases?

11 A. They were both settled.

12 Q. Settled, okay.

13 Okay. So no trial; right?

14 A. There -- there was no trial and it was for a
15 fully disclosed amount.

16 Q. Okay. Any other litigation against you
17 other than those two cases that we talked about, any
18 litigation of any type?

19 A. No.

20 Q. Have you ever had a disciplinary action
21 against you by any medical board?

22 A. No.

23 Q. Have you ever been arrested or convicted of
24 a crime?

1 A. No.

2 Q. Okay. We discussed -- okay. Other than
3 being retained in the Garcia case as an expert and in
4 this -- in the case where you were retained as an
5 expert that you mentioned before where you did a
6 deposition, have you ever been retained as an expert
7 in litigation, other than those two instances you've
8 already mentioned?

9 MR. SNELL: Hold on, hold on. I'm going to
10 instruct you. To the extent you have not been
11 disclosed, you should be mindful of that and not
12 identify those cases. To the extent you have not
13 been disclosed, either by deposition, expert
14 report, doing an IME of the plaintiff, under the
15 rules, depending upon where you may have been
16 retained, that is confidential information.

17 A. I gave testimony on Cavness.

18 Q. (By Mr. De La Cerda) Okay. Other than
19 Cavness, Garcia and then this other case involving
20 urinary incontinence after vaginal delivery, any
21 other cases where you've been designated as an
22 expert?

23 A. On -- on Ramirez.

24 Q. Right. Is there a name to the case where

1 you were the expert for the defense on the urinary
2 incontinence after the vaginal delivery? Do you
3 remember a name?

4 A. I cannot recall.

5 Q. Okay. That would just make it easier to
6 reference, but ...

7 Okay. In all four of these cases, the
8 Cavness case, the Garcia case, the Ramirez case and
9 the case involving urinary incontinence after vaginal
10 delivery, all four of those cases you were retained by
11 the defense; correct?

12 A. That's correct.

13 Q. You've never testified for the plaintiff as
14 an expert; is that right?

15 A. I have not testified for the -- for a
16 plaintiff. I have given opinions as part of the State
17 of Florida Prosecution Unit, which is actually known
18 as the Department of Health, Department of Health now.
19 It's work that I have done for years for the
20 Department of Health.

21 Q. Are these like criminal investigations into
22 doctors or what -- what is it?

23 A. You know, that's why they eliminated the
24 Prosecution Unit name because it sounds criminal, so

1 now we all understand that it's -- it's any complaints
2 that have been brought against a physician in my -- in
3 my specialty, I and the board feels that needs to be
4 reviewed, I review.

5 Q. Okay. And how long have you been doing
6 that?

7 A. Close to 15 years.

8 Q. 15 years. Okay.

9 Let's talk briefly about your role as a
10 consultant for Ethicon outside of litigation. Okay?
11 So this word "litigation" is not contemplated, this is
12 just your role as a consultant in what -- helping out
13 what Ethicon does in its normal business. Okay?

14 So, first of all, in the past, you have been
15 hired as a consultant for Ethicon; correct?

16 A. Yes.

17 Q. Okay. And do you recall when you were first
18 hired as a consultant for Ethicon?

19 A. It may have been just after the year 2000,
20 2002. I don't recall the specific year.

21 Q. Okay. But early 2000s?

22 A. About -- about that time.

23 Q. Okay. And what was the purpose of you being
24 hired on as a consultant when you first started?

1 A. Initially, I was given the opportunity to --
2 to dissect cadavers and to put together the anatomy
3 for the dissection in specimens as it would apply to
4 the use of products.

5 Q. Okay. So I'm having a little trouble
6 understanding what that might be. Explain to me what
7 you would do, then, on a typical day involving that
8 particular role.

9 A. It changed. It changed over the -- over the
10 years. I started dissecting and teaching and being
11 involved with my peers on how to use the different
12 products and it was just an interest that I -- that I
13 had very early in my career about surgical anatomy.
14 So I just expanded that and I was given the
15 opportunity while -- I was given instruments to work
16 in the gallery.

17 Q. Okay. Did you have a title when you first
18 began as a consultant for Ethicon?

19 A. No.

20 Q. Okay. Were there defined duties that you
21 had when you first started out as a consultant?

22 MR. SNELL: Form.

23 A. No, nothing -- nothing that was defined as
24 different task.

1 Q. (By Mr. De La Cerda) Okay. They didn't
2 have, like, a job description that was given to you
3 when you first started?

4 A. No.

5 Q. Okay. And so in this role involving
6 dissecting cadavers, where you were teaching other
7 peers about how to use the Ethicon products, was that
8 a role that remained consistent throughout your time
9 as a consultant for Ethicon or did it change over
10 time?

11 A. It changed based on the needs that they had,
12 for what -- what they understood was my expertise.

13 Q. Okay. So let's do this. So the beginning
14 is approximately the beginning of the 2000s. Has that
15 con- -- has that role as a consultant for Ethicon
16 ended or do you continue to be a consultant for
17 Ethicon?

18 A. No, I don't consult with them anymore beyond
19 the legal.

20 Q. And so when did your role as a consultant
21 end?

22 A. Just -- just about the time that the
23 products -- the prolapse products were
24 decommercialized.

1 Q. Okay. So is that 2012, approximately?

2 A. Yes.

3 Q. Okay. So I guess that's about ten years of
4 acting as a consultant; is that fair?

5 A. Yes.

6 Q. Okay. So the manner in which your role as a
7 consultant changed, was it really in -- in regard to
8 the products themselves, what kind of product you were
9 teaching, or is there some other way in which it
10 changed?

11 A. It changed. It changed based on what --
12 whatever was understood that there was a need.

13 Q. Okay. Can you give me some examples?

14 A. Initially, it was seeing the products, how
15 they would work, and nothing -- nothing in terms of
16 experiment or research and development. It was more
17 on how -- how to reproduce their use in the -- in the
18 operating room.

19 Q. Mm-hmm.

20 A. And then I was able to -- to see -- to see
21 how -- how the products were actually implemented
22 in -- in the surgical environment. And there was a
23 time in which I would just see other surgeons that
24 were consultants. And then there was a time in which

1 I would go to and meet with -- with a group at Ethicon
2 and give a conference on anatomy or I would take them
3 to the lab and show them the anatomy.

4 Q. Mm-hmm.

5 A. And then there was a time in which I
6 actually wrote a manual of how to dissect -- dissect a
7 specimen, make the best of that dissection.

8 Q. Okay. But tell me about this manual. What
9 is it that you'd be dissecting -- so tell me, what was
10 the content of this manual?

11 A. The labs -- the labs using specimens are
12 very unique and they're very -- they're very
13 expensive.

14 Q. Okay.

15 A. And the whole setup of getting a good
16 specimen. And what we call "specimens" is a portion
17 of a person and there -- there are certain things that
18 we have to follow over the years, over the last 25
19 years that I have learned dissecting and understanding
20 the anatomy. One of the most complex anatomies that
21 you can have in any other -- other part of the body.
22 So when we -- when we did this and there's -- my
23 interest was that, and I verbalized that, that we
24 could make the best use of these specimens in the lab.

1 Q. Mm-hmm.

2 A. And not only that it would be -- it would be
3 the best use, but also that it would be a systematic
4 approach in the same way that first-year medical
5 students are taught anatomy.

6 Q. Mm-hmm. Okay.

7 A. So to get -- to make that organized and to
8 make that systematic and to make that consistent, then
9 there was -- there was a proposal for a manual. That
10 was just one part of -- of what could be done in -- in
11 the lab- -- laboratory.

12 Q. And this was a manual that was done for
13 Ethicon; right?

14 A. It was done for -- for them, but I think it
15 was -- there were other -- other considerations
16 beyond -- beyond anatomy and probably did not get
17 developed, but I got the -- I got the opportunity to
18 take my pictures and actually put it in -- on my thumb
19 drive with presentations, which you're going to be
20 requesting.

21 Q. Okay. Are these cadaver specimens, they're
22 reused for purposes of teaching doctors how to do --
23 how to, for example, implant Ethicon's products;
24 right?

1 A. Well, cadavers are used in sections and,
2 obviously, we're going to -- we're going to use a
3 section that pertains to the procedure that we're
4 doing and they -- they form the basis of teaching
5 anatomy from the first year of medical school.

6 Q. Do they -- do the cadaver -- I guess the
7 portions of the cadaver that are used to present how
8 to implant products, do they eventually get used, to a
9 certain extent, to where, okay, we can't use this
10 cadaver anymore, like it's been used too much for this
11 particular presentation?

12 A. You can -- you can always make -- make the
13 best of what you're examining. So, yeah, if there is
14 a portion that is used, you can always go to different
15 things that you can teach from the -- from the
16 cadaver. That's highly dependent on the condition of
17 the cadaver.

18 Q. Yeah.

19 A. It's highly dependent on how it was
20 prepared. It's highly dependent on how those
21 individuals that are doing the dissection know how to
22 do it.

23 Q. Okay. Okay. So going back to your role as
24 a consultant for Ethicon and what it is that you did,

1 have you now explained all the various things that you
2 did as a consultant on behalf of Ethicon?

3 MR. SNELL: Form.

4 A. I -- I actually look at presentations. In
5 addition to, I look at presentations. I would make a
6 presentation to -- to different groups within Ethicon.

7 Q. (By Mr. De La Cerda) You would do
8 presentations for other physicians about Ethicon's
9 products; is that correct?

10 A. About Ethicon products and about the
11 condition itself.

12 Q. Okay. And did the presentations that you do
13 to other doctors for Ethicon include TVT, TVT-O,
14 Gynemesh, Prolift and Prosima?

15 A. It was TVT-O, TVT-Secur, Gynemesh, Prosima,
16 and Prolift.

17 Q. Any reason why you didn't do presentations
18 on regular TVT or TVT-R?

19 A. I had a -- I had a preference for the
20 transobturator slings.

21 Q. Had you used in the past a TVT Retropubic
22 for your patients?

23 A. Yes.

24 Q. And why is it that you preferred the TVT-O

1 over the TVT?

2 A. I felt I could do the same with less risk.

3 Q. And what risk are you specifically talking
4 about?

5 A. Getting to the bladder. Very rare, but
6 potential getting to the bowel and getting to a major
7 blood vessel.

8 Q. You've testified before that you've made --
9 you've made about \$100,000 a year as a consultant for
10 Ethicon; is that right?

11 A. That -- I may have testified to that number,
12 yes.

13 Q. Okay. And so if we're talking about ten
14 years, we're talking about approximately a million
15 dollars you made as a consultant for Ethicon; correct?

16 MR. SNELL: Form.

17 A. No, it doesn't -- doesn't get to that
18 because it wasn't -- it wasn't like a salary. It was
19 in a -- in a need and there were years that it was
20 \$3,000.

21 Q. (By Mr. De La Cerda) Do you have an
22 approximation of how much you made total as a
23 consultant for Ethicon?

24 A. I -- I think the largest and the best year,

1 most active year, I may have done about 100. But
2 that -- that's probably one or two years.

3 Q. Do you have a range, total, for all the
4 years that you acted as a consultant for Ethicon?

5 A. Never -- never really counted.

6 Q. Do you have any documentation of that, of
7 what the numbers might be?

8 A. My 1099s that I receive or my tax returns.

9 Q. Okay. And if Ethicon has records of that,
10 you'd, of course, defer to whatever those records say;
11 right?

12 MR. SNELL: Objection, form, foundation.

13 A. As -- as long as they correlate with my
14 1099.

15 Q. (By Mr. De La Cerda) Right. So if they
16 had records of the 1099s, which I assume they do,
17 you would defer to whatever those numbers are;
18 right?

19 A. I -- I would defer to that.

20 Q. When you've presented on Ethicon's products,
21 where have those presentations occurred,
22 geographically?

23 A. You know, it happened mostly here either in
24 Florida or in New Jersey. Occasionally, I would go

1 to -- to other cities, Austin, Toronto, Dallas,
2 Boston. Never -- never too -- never too far. I -- I
3 made that decision that I wasn't going to go, let's
4 say, to the Northwest or California maybe once because
5 I have a practice that I have to take care of.

6 Q. Right. I guess you have the advantage, too,
7 of being in Miami, doctors would want to come to you
8 for the -- were there many presentations here in
9 Miami, too?

10 A. There -- there were -- yeah, there were some
11 in Miami, absolutely.

12 Q. Okay. When the presentations were out of
13 town, Ethicon, of course, covered your -- your meals,
14 your lodging, your transportation; right?

15 A. With- -- within the -- within the range that
16 was specified for that kind of traveling.

17 Q. How was that done? How was the range
18 specified?

19 A. We -- we were required to take a course on
20 guidelines for -- as consultants for any kind of
21 industry.

22 Q. Mm-hmm. And do you recall any of what those
23 guidelines were?

24 A. I -- I do recall there was -- there were

1 specifics on which hotel we could stay and -- and no
2 first class traveling, and there was compensation, if
3 we would drive, for the miles --

4 Q. Okay.

5 A. -- and there were also some -- some limits
6 on what we could spend on food, although most of the
7 time food was provided there.

8 Q. Do you know whether Ethicon believed you to
9 be a good preceptor or teacher on its TVT products?

10 A. I -- I think that they visualized me as a
11 good surgeon with good common surgical sense.

12 Q. And I just used the term "preceptor," I need
13 to make sure that's understood. Could you explain to
14 us what the term -- what your understanding of the
15 term "preceptor" is?

16 A. The preceptor is -- is a term that was, I
17 believe, from mostly the marketing people. I never
18 really saw myself as a preceptor.

19 Q. Mm-hmm.

20 A. I saw myself as a surgeon. And if you ask
21 any of my colleagues, they don't see me as a
22 preceptor. Through the course -- through the years, I
23 have seen doctors that have seen me for every single
24 product and we always ended up talking about the same

1 thing, the anatomy and the surgery.

2 Q. Mm-hmm. And so preceptor, I guess that's
3 used as some version of saying that someone's a
4 teacher; is that right?

5 A. I -- I think it was an internal term for --
6 for them, preceptor, and it's -- it doesn't get to the
7 level of a teacher or a professor, it doesn't have
8 that -- that responsibility. It doesn't have -- it
9 has mostly the role of showing something, of
10 demonstrating.

11 Q. Okay. Do you know whether Ethicon ever
12 criticized the way in which you taught other
13 physicians in preceptorships?

14 A. They -- they did not have a specific
15 criticism and they -- they would ask, whenever they
16 would bring someone to see me operating, that they had
17 a -- that the doctors could get to see as much as they
18 could see in terms of the variety of procedures, but,
19 obviously, that -- the cases are what the cases are.

20 Q. Yeah.

21 A. You show what you have.

22 Q. Ethicon -- I guess, in other words, Ethicon
23 never said -- made you personally aware of any
24 specific criticisms of any type of the manner in which

1 you were teaching other doctors how to perform these
2 procedures; right?

3 MR. SNELL: Form.

4 A. There -- there was -- it was a relationship
5 with -- with a lot of respect for what I did, for what
6 I brought to the -- to their table.

7 Q. (By Mr. De La Cerda) Okay. So the answer
8 is no, you never became aware of any criticisms;
9 right?

10 A. No.

11 Q. In August of 2011, you decided to stop
12 preceptorships due to the FDA situation; correct?

13 A. I -- I -- there was a communication that
14 said we -- we need to look at this and we need to look
15 at what the FDA is saying, and everybody needs to be
16 on the same wavelength.

17 Q. Mm-hmm. And so what -- how long did that
18 last, that decision to suspend or interrupt your
19 preceptorships?

20 A. I don't -- I don't remember exactly how --
21 how long did it last or if I ever went back and did a
22 consultation in other -- other regards. It's -- it
23 was just a gen- -- probably a general concern from all
24 sides.

1 Q. Okay. Just to make sure. So you're unsure
2 whether, in August of 2011 when you decided to stop
3 the preceptorships due to the FDA concern, you're
4 unsure whether you went back to consulting for Ethicon
5 after that point?

6 A. Yeah, I --

7 MR. SNELL: Objection to form.

8 Go ahead.

9 A. -- I did -- I did not cut completely at that
10 time and actually it was -- it was me relating, I
11 believe, to Bob Zipfel, who was the professional
12 education manager --

13 Q. (By Mr. De La Cerda) You said Bob Zipfel?

14 A. Zipfel, Z-i-p-f-e-l.

15 -- relating that we -- we need to get clear
16 on the -- on the message and we need to include
17 whatever is out there and be transpiring about it.

18 Q. And so what was it that you decided, along
19 with Ethicon, to make clear about the message
20 involving this issue?

21 MR. SNELL: Objection, form, Ethicon.

22 A. As far as I remember from my side, it was
23 let's -- let's look at this. It was -- that's more of
24 the attitude that I can recall.

1 Q. (By Mr. De La Cerda) Do you remember ever
2 discussing this FDA issue with doctors during a
3 consultation on behalf of Ethicon?

4 A. I -- I don't remember that.

5 Q. Okay. Do you remember discussing this issue
6 at all with any doctors in regard to Ethicon products?

7 MR. SNELL: Objection, form.

8 Go ahead.

9 A. I don't -- I don't remember specifics of
10 talking to a specific doctor or being at a conference
11 just talking about -- about this.

12 I don't even remember if it was 2007, 2008,
13 or -- I don't remember which time frame it was. I
14 am -- you know, I became aware of this, that I say at
15 one point we need to stop or we need to review, we
16 need to revise it, or we need to look at it, but it
17 was never like, oh, no, I'm not teaching anymore, I'm
18 not demonstrating anymore for you.

19 Q. (By Mr. De La Cerda) Mm-hmm.

20 A. That's what I can recall. That's the best
21 of my recollection right now.

22 Q. Why is it important when the FDA puts out a
23 warning, like they did in 2011, to investigate and
24 look into what -- the reason behind the warning?

1 MR. SNELL: Form.

2 A. It's because the results and the clinical
3 experience that we're getting was different from what
4 we were seeing in those -- in those reports.

5 Q. (By Mr. De La Cerda) Okay. So the FDA
6 warning came out in July of 2011, was that a
7 surprise to you?

8 A. It was -- it was a surprise in 2008 and it
9 was in 2011. What I -- what I thought is evidence is
10 going to come in and is going to show -- it's going to
11 solve this difference that a group of doctors may have
12 with other group of doctors.

13 Q. You're familiar with the Abbott study that
14 came out -- it came out probably in 2014, I think.
15 Abbott -- the lead author is Abbott, Mickey Karram is
16 one of the authors as well. And one of the
17 discussions they have is that many times when -- I
18 think about half the time, at least -- when a patient
19 has a complication involving a mesh implant, whether
20 it be a sling or a pelvic organ prolapse mesh, they do
21 not return to the physician that implanted it.

22 Are you aware of that phenomenon?

23 MR. SNELL: I'm going to object to the
24 foundation on that.

1 Go ahead.

2 A. I -- I've heard about that. I never
3 believed that that's the case.

4 Q. (By Mr. De La Cerda) Okay. And why is
5 that?

6 A. Because of my own experience, because of
7 my -- the experience that I have heard from my
8 colleagues. That's -- that's not what our experience
9 is.

10 You -- you may have a small percentage that
11 may not come back, but in my community, for example,
12 we all know, we all communicate. There are four, five
13 board-certified female pelvic medicine in the whole
14 stretch all the way to Boca from here. We know each
15 other and -- and the doctors also communicate with us,
16 so there is a lot of communication there.

17 If there is a loss to follow up, it might be
18 on the clinic setting, when you have these clinics,
19 other -- other types of settings, but not in the
20 private-practice setting.

21 Q. If a patient went to go receive treatment
22 for a complication in a different city that's
23 something like Dallas, for example, would you
24 necessarily find out about that?

1 A. I may not -- I may not find out, but I know
2 that most of the time it's not even dependent on the
3 patient. They -- they come and they communicate with
4 me. I've had patients that have gone to New York,
5 they come back and tell me this was my experience.

6 Q. You mentioned something interesting because
7 you're -- and I hear this from physicians every time.
8 I think this is our natural inclination.

9 You mentioned in your experience you haven't
10 seen that happen. Ultimately, you would agree that
11 your personal experience on that issue, on whether
12 people come back to the primary physician or not, is,
13 at best, only anecdotal. Do you agree with that?

14 A. It's -- it is definitely a portion that is
15 anecdotal. I do talk to so many of my colleagues and
16 if it's anecdotal, it repeats a lot.

17 Q. Yeah, I get that. I mean, here you are in a
18 community where you do actually know all these
19 physicians that do this thing and if the general
20 consensus is that this is what's happening, it can
21 certainly feel like this is the reality of it. But
22 ultimately we've got a study that was done that looked
23 at many people -- by the way -- strike that.

24 Are you familiar with this study, the Abbott

1 study? Like have you actually reviewed it?

2 A. I -- I did not read that study complete, no.

3 Q. Okay. Then I'm going to move on to another
4 subject then.

5 Going back to acting as a consultant, have
6 you ever acted as a consultant for any other
7 pharmaceutical or medical device company?

8 A. For pharmaceuticals, I work for ALZA
9 Pharmaceuticals.

10 Q. Is that --

11 A. A-L-Z-A. When they came -- they came in
12 with a new anticholinergic.

13 Q. I'm sorry, what is that?

14 A. ALZA, A-L-Z-A, Pharmaceuticals.

15 Q. And the drug?

16 A. It was Ditropan XL.

17 Q. Ditropan XL.

18 And what was that drug for?

19 A. For overactive bladder.

20 Q. How long did you work as a consultant for
21 ALZA Pharmaceutical?

22 A. About two years.

23 Q. And do you recall approximately when that
24 was?

1 A. It was when I was starting the urogynecology
2 center here, so it may have been '96, '97.

3 Q. Any other medical device or pharmaceutical
4 companies that you've acted as a consultant for, other
5 than ALZA and Ethicon?

6 A. I -- oh, I worked for Ethicon on the
7 laparoscopy area around 1994, internationally.

8 Q. Was that just for one year?

9 A. A year, year and a half, yes.

10 Q. Any other consulting work for pharmaceutical
11 or medical device companies?

12 A. You know, I may have -- I may have had
13 representatives from one or two companies that say I
14 want you to go ahead and teach me how my product works
15 and -- and teach me how -- how is it that urge
16 incontinence is managed.

17 And I may say, okay, and some of them may
18 give me a check, which I ended up either giving to the
19 Residents Fund in Puerto Rico or did something with
20 it, but it was something sporadic.

21 Q. Would these be some of the other mesh
22 manufacturers, like Boston Scientific or American
23 Medical Systems, companies like that?

24 A. No, I did not -- I -- I never did consulting

1 for any other company on mesh but Ethicon.

2 Q. Do you remem- -- do you recall the names of
3 the companies that you did this urge incontinence work
4 for?

5 A. I think it may have been Detrol or --

6 Q. Detrol?

7 A. -- Enablex. I don't remember the name of
8 the company.

9 Q. Okay. And do you recall the approximate
10 years that would have happened?

11 A. No.

12 Q. Okay. Now let's get to the part that's
13 always the most tedious. What is it that you brought
14 here today with you?

15 A. I brought here in compliance with the papers
16 served for the subpoena, I brought my CV --

17 You have a copy?

18 Q. Yes.

19 A. -- and a USB, in which I have any file that
20 I had on my computer that when I -- when I was at
21 Ethicon, I just downloaded my presentations.

22 Q. Okay.

23 A. And there were some videos of surgeries
24 here.

1 Q. Okay.

2 A. And I brought my biomechanics books and the
3 book that Ethicon put together for -- about Gynemesh
4 and Prolift, and I did -- the one on Gynemesh is about
5 my slides.

6 And I -- but all the materials that were
7 cited in my report and materials for prolapse, my
8 materials for case specifics for tomorrow,
9 depositions, and the Prolift monograph.

10 Q. Okay. And that's it?

11 A. I am missing the white paper on
12 hydrodissection. That I could not find at all. I
13 will make it my business to provide to you.

14 MR. SNELL: Peter, I think we provided --
15 there's thumb drives that my office did, too.

16 MR. DE LA CERDA: Are those all -- those are
17 the case-specific ones?

18 MR. SNELL: Case and general.

19 Q (By Mr. De La Cerda) Okay. So that we're
20 not taxing the court reporter too much on copying
21 and the like -- first of all, are the materials that
22 you brought, other than the books, are those all
23 copies?

24 A. Yes.

1 Q. Okay. What -- I guess what I would be most
2 interested in is what you brought that is not on the
3 Reliance List. Because most of -- just about
4 everything on the Reliance List we can find.

5 And so, first of all, these book chapters,
6 are those referenced in the Reliance List, these books
7 that you have listed here in -- here in front of us?

8 A. No, they're not.

9 Q. Okay. So are there particular portions of
10 those books that are relevant to your opinions or is
11 it the whole book?

12 A. I -- I -- there are portions that are
13 relevant to the way I see slings and meshes work.

14 Q. Okay. Okay. And can you tell us what -- is
15 it a chapter? Is it a particular passage or --

16 A. They're -- they're chapters.

17 Q. Okay. And as far as you know, they are not
18 referenced in the Reliance List at all?

19 A. They're -- they're not, that's why I brought
20 them, and the same with the -- with the USB.

21 Q. Okay. So, again, first of all, let's do
22 this. Let's separate out the items that are not on
23 the Reliance List so we can make sure and mark and
24 identify those and -- so let's do that.

1 So the books that are here, these are the
2 ones not on the Reliance List; right?

3 A. Yes, sir.

4 Q. And then you've got -- and I'm going to mark
5 each of these in a second-- the USB that you brought;
6 correct?

7 A. Yes.

8 Q. Okay. Anything else, other than those and
9 other than the case-specific USBs that you brought,
10 anything else that is not on the Reliance List?

11 A. The only one missing that I -- that I didn't
12 bring today that I'm -- I made my best effort to bring
13 you is the white paper that I wrote on hydrodissection
14 along with Dr. Lucente and -- yeah.

15 MR. DE LA CERDA: Okay. So as far as
16 marking these, anything -- any particular way you
17 want to -- you want to do this, Burt?

18 MR. SNELL: It doesn't matter. This stuff
19 here is like all general stuff, from his general
20 reports and the Reliance List, and I think it's
21 probably duplicative of the hard copies and also
22 specific citations in the materials. I was just
23 trying to sort out --

24 MR. DE LA CERDA: The case-specific --

1 MR. SNELL: We sent so many cases to the
2 thumb drives and stuff like that over time. This
3 is general. If you want a copy -- I don't even
4 know what's on these. I know they reproduced --
5 I think they were supposed to reproduce the
6 materials list, but I haven't checked them to
7 see.

8 MR. DE LA CERDA: Okay.

9 MR. SNELL: I mean, I agree, I think you
10 ought to mark definitely the stuff that was just
11 kind of general -- general impression, the
12 general stuff that he brought.

13 MR. DE LA CERDA: Yeah.

14 MR. SNELL: And if you want to -- mark
15 whatever you want, you know.

16 MR. DE LA CERDA: Yeah.

17 MR. SNELL: These just have his reports and,
18 like he said, everything that he cited -- here's
19 some articles in here. You can tell him, those
20 are probably cited within there.

21 THE WITNESS: This is cited and this is
22 cited, this is cited, too. This is a monograph.
23 These two are new. These two are new.

24 MR. SNELL: Is there anything in this?

1 Here.

2 THE WITNESS: This is not cited. Cited,
3 cited.

4 MR. DE LA CERDA: I think we're going to
5 have to do this the long way.

6 Q. (By Mr. De La Cerda) Okay. All right.
7 So here's what I want to do. Just to make --
8 because I don't want to miss anything, because it
9 looks like you might have some newer stuff. Maybe
10 you looked at some additional research or something
11 and found some newer stuff, but what I want to do
12 is, let's just -- I want to stack it by category and
13 then I'll mark each stack.

14 So the easiest way to do it, for me, at
15 least, is do it by -- you know, we do ours like this,
16 too. We're going to do it by stacks that involve
17 certain subject matters, like, for example, everything
18 you've brought today that is a medical literature,
19 let's put that all into one stack and I'm going to
20 mark that. Okay? And then everything you brought
21 today that would be Ethicon documents, internal
22 documents, we'll -- we'll mark that. And then
23 everything you brought today that would be depositions
24 or testimony that you reviewed and relied on, we'll

1 mark that.

2 A. This -- this is all medical literature.

3 Q. Okay. So of the stuff that we've got here,
4 what -- we have a stack here that's medical
5 literature.

6 A. Yes.

7 Q. Are any of the binders medical literature?

8 A. All of it.

9 MR. SNELL: It's all literature. It's the
10 stuff cited directly in his reports.

11 MR. DE LA CERDA: Okay.

12 MR. SNELL: Do you use footnotes or --

13 THE WITNESS: Yes, I did. Every footnote --

14 MR. SNELL: It should correspond in here.

15 MR. DE LA CERDA: And then this stack here
16 that I've got is all not in the Reliance List;
17 right?

18 MR. SNELL: I will say with the -- I'm about
19 99 percent sure that this would have been. The
20 Prolift monograph, surgeons' monograph is
21 definitely on his materials list and he's
22 referenced that before. This is his actual --
23 this is your actual preceptor book. I don't know
24 what you called it.

1 THE WITNESS: It's the book that Ethicon
2 made on Gynemesh and Prolift and they -- and I
3 put together the first one.

4 MR. SNELL: I think that that's on his
5 materials list, too, but just in case, I mean he
6 brought that. That's his actual one.

7 The Surgeons' Resource Monograph, I know for
8 a fact, has got to be on there.

9 MR. DE LA CERDA: So what I'm going to do
10 is --

11 MR. SNELL: He brought that. That's
12 obviously his originals.

13 Q. (By Mr. De La Cerda) I'm not going to
14 mark these, I'm just going to identify them.

15 So today you brought with you the Gynecare
16 Prolift and the Gynecare Gynemesh Preceptor
17 Presentation Kit; correct?

18 A. Yes.

19 Q. And these are your -- this is your original?

20 A. Yes.

21 Q. Now, do you have this available at all
22 electronically?

23 A. No.

24 MR. DE LA CERDA: Okay. Do you know if

1 these are available electronically?

2 THE WITNESS: There might be a CD.

3 MR. SNELL: I think if you open the inside
4 cover, there are CDs.

5 THE WITNESS: There might be a CD there,
6 yes.

7 MR. DE LA CERDA: Because what I would like
8 to do is get a copy of this, just electronically,
9 because this -- so it's not copied -- so the
10 court reporter doesn't have to copy it.

11 So how do you want to do that?

12 MR. SNELL: Do you want -- can I take it?

13 THE WITNESS: Yeah. Send it back because
14 it's the only one I have.

15 MR. SNELL: I mean, there's two ways. We
16 can either have the court reporter do it and then
17 it's going through multiple people's hands or if
18 you give it to me, I'll make color copies of
19 everything, the cover, the back, the pages, and
20 then I'll burn the CDs.

21 MR. DE LA CERDA: Okay.

22 MR. SNELL: I'll basically give you an exact
23 copy of what you're holding and then I'll
24 actually make a copy for myself, because I don't

1 have a copy of that exact one, and then I'll give
2 it back to the doctor.

3 MR. DE LA CERDA: Okay. So then that --

4 MR. SNELL: Let's make a record for that, a
5 note for that.

6 MR. DE LA CERDA: So for the record, then,
7 that will be Exhibit 1. I'm just going to put
8 this here for now.

9 MR. SNELL: I will make a note I need to
10 take that and copy it.

11 MR. DE LA CERDA: So for the record,
12 Exhibit 1 is the Gynecare Prolift and Gynecare
13 Gynemesh PS Preceptor Presentation Kit.

14 (Plaintiff's Exhibit No. 1 was marked for
15 identification.)

16 MR. DE LA CERDA: Exhibit 2 is going to be
17 Dr. Sepulveda's original Prolift Surgeon's
18 Resource Monograph.

19 (Plaintiff's Exhibit No. 2 was marked for
20 identification.)

21 Q. (By Mr. De La Cerda) Now, Exhibit 3, I'm
22 going to mark, these are -- this is medical
23 literature that you've gathered, Dr. Sepulveda;
24 correct?

1 A. Yes.

2 Q. And this is medical literature that happens
3 not to be on the Reliance List; correct?

4 A. That's correct.

5 MR. DE LA CERDA: So I'm marking that as
6 Exhibit 3.

7 (Plaintiff's Exhibit No. 3 was marked for
8 identification.)

9 MR. SNELL: Just for the record, since,
10 obviously, my firm was the one who made the
11 Reliance List, I do believe that one of those may
12 be on there.

13 MR. DE LA CERDA: Okay.

14 MR. SNELL: Like the ACOG committee opinion
15 on vaginal prolapse mesh, I'm pretty sure that's
16 on the materials list, if I even have his
17 materials list.

18 You can keep doing that.

19 MR. DE LA CERDA: Okay.

20 MR. SNELL: But I'm pretty sure that would
21 have been sent.

22 MR. DE LA CERDA: Prosima IFU, I'm sure that
23 was on the Reliance List.

24 MR. SNELL: All that stuff is on the

1 Reliance List.

2 THE WITNESS: I can take that back.

3 MR. SNELL: All the professional education
4 slides, those are on there.

5 Q. (By Mr. De La Cerda) All of these are
6 also on the Reliance List; right? Okay. So I'm not
7 going to mark those.

8 And then, now, books. Let's go through each
9 of these.

10 First of all, I'm looking at a book called
11 "Biomechanics: Mechanical Properties of Living
12 Tissues," the Second Edition, published by Springer
13 and the author is Y.C. Fung, F-u-n-g.

14 Do you have specific chapters that you can
15 identify within this book that you rely on?

16 A. Yes. Chapter 7.

17 Q. Okay. Any others?

18 A. No, 7.

19 MR. DE LA CERDA: Okay. So I'm going to
20 mark this book as Exhibit 4 and then if we can
21 just get a copy of chapter 7, just chapter 7,
22 then the book can be returned.

23

24

1 (Plaintiff's Exhibit No. 4 was marked for
2 identification.)

3 Q. (By Mr. De La Cerda) You've also brought
4 a book entitled "Introductory Biomechanics From
5 Cells to Organisms." The author is -- or authors
6 are C. Ross Ethier, E-t-h-i-e-r, and Craig A.
7 Simmons. It looks like this is published by
8 Cambridge University Press.

9 Are there any chapters or passages within
10 this book --

11 A. Yes.

12 Q. -- that supports your opinions?

13 A. Chapter 9.

14 Q. Okay. Great. I'll mark this book,
15 "Introductory Biomechanics," as Exhibit 5 and then
16 we'll just get a copy of that particular chapter you
17 referenced, chapter 9.

18 (Plaintiff's Exhibit No. 5 was marked for
19 identification.)

20 MR. DE LA CERDA: Another book you brought
21 is called "Biomaterials and Biomedical
22 Engineering" published by Trans, T-r-a-n-s, Tech,
23 T-e-c-h, Publications. This one is edited by W.
24 Ahmed, A-h-m-e-d, N. Ali, A-l-i, and A. Öchsner.

1 It's O-umlaut-c-h-s-n-e-r.

2 And I'm marking this book as Exhibit 6.

3 (Plaintiff's Exhibit No. 6 was marked for
4 identification.)

5 Q. (By Mr. De La Cerda) Are there any
6 chapters or passages in that book that you rely on?

7 A. Yes.

8 Q. What are they?

9 A. Chapter 12.

10 Q. Okay. Thank you. And then we'll get a copy
11 of that and return the original book to you.

12 Okay. Now, you've also -- the other
13 material other than the case-specific materials, the
14 other material -- materials you've brought with you
15 have all been cited either in your report or in your
16 Reliance List; correct?

17 A. That's correct.

18 Q. Okay. Great. Now the last thing I'm going
19 to do --

20 MR. SNELL: Peter, one thing --

21 MR. DE LA CERDA: Yes.

22 MR. SNELL: -- for clarification. I had
23 mentioned I thought the ACOG physician statement
24 from 2011 on transvaginal POP mesh was in. It's

1 on his materials list. For some reason these
2 don't have page numbers, but it's under "other
3 materials."

4 MR. DE LA CERDA: Okay.

5 MR. SNELL: I put a check next to it.

6 MR. DE LA CERDA: Okay. Great. All right.

7 Q. (By Mr. De La Cerda) Now, the last bit of
8 materials that you brought with you are various
9 thumb drives. What are these thumb drives?

10 A. These are the thumb drives that have the
11 articles that you see in these binders.

12 Q. Oh, I see. Okay. So actually, it would be
13 nice to go ahead and mark these. So we have four
14 different thumb drives. Each of these thumb drives is
15 actually labeled with a product, as well. So there is
16 Sepulveda TVT - TVT-O, Sepulveda TVT-S, Sepulveda
17 Prolift, and then there's another Sepulveda TVT-S, I
18 don't know if that's just a repeat, but I'll mark each
19 of these with its own sticker. We're on 6.

20 So I'm marking as Exhibit 7 to your
21 deposition the thumb drive that has Sepulveda TVT and
22 TVT-O and this thumb drive contains reliance materials
23 and materials cited in your report; correct?

24 A. Yes.

1 (Plaintiff's Exhibit No. 7 was marked for
2 identification.)

3 Q (By Mr. De La Cerda) Then I'm marking as
4 Exhibit 8, Sepulveda TVT-S, and these are also
5 documents referenced in your Reliance List and your
6 report relating to TVT-S; correct?

7 A. Yes.

8 (Plaintiff's Exhibit No. 8 was marked for
9 identification.)

10 Q (By Mr. De La Cerda) Then I'm marking as
11 Exhibit 9 to your deposition the thumb drive that
12 has -- that's marked Sepulveda Prolift, and these
13 are materials referenced in your Reliance List and
14 your report for Prolift; correct?

15 A. Yes.

16 (Plaintiff's Exhibit No. 9 was marked for
17 identification.)

18 MR. DE LA CERDA: Do you know why there is a
19 second TVT-S one?

20 MR. SNELL: I have no idea.

21 MR. DE LA CERDA: I'll just mark it as
22 another one.

23 MR. SNELL: Somebody might have just made
24 two copies. I can open it up and look at it real

1 quick.

2 MR. DE LA CERDA: I'll just mark it.

3 Then I'm also marking as Exhibit 10 to your
4 deposition a second thumb drive labeled
5 "Sepulveda TVT-S," which I assume is also
6 reliance materials and documents referenced
7 within your report; correct?

8 A. Yes.

9 (Plaintiff's Exhibit No. 10 was marked for
10 identification.)

11 MR. DE LA CERDA: Case-specific, they can
12 deal with that.

13 THE WITNESS: I need to -- to -- I did not
14 remember seeing the Bianchi-Ferraro --

15 THE COURT REPORTER: I'm sorry, the --

16 THE WITNESS: I do not remember seeing the
17 Bianchi-Ferraro paper on TVT-Secur and TVT-O.

18 MR. SNELL: Is it in this pile?

19 THE WITNESS: I want to double-check that
20 because I --

21 MR. SNELL: Bianchi-Ferraro?

22 THE WITNESS: Bianchi-Ferraro, which I
23 referred to in the Garcia deposition.

24 MR. SNELL: Okay. This is other literature.

1 You want to give that to him. That's additional.

2 THE WITNESS: Additional.

3 MR. DE LA CERDA: Oh, okay. All right. I'm
4 also marking as Exhibit 11 medical literature
5 that you've handed to me.

6 (Plaintiff's Exhibit No. 11 was marked for
7 identification.)

8 Q (By Mr. De La Cerda) What is this medical
9 literature?

10 A. That is -- this is medical literature about
11 the -- one case report of clear cell carcinoma of the
12 vagina and there's -- in a patient that has had a
13 midurethral sling. This is the response to that
14 article.

15 Q. (By Mr. De La Cerda) Okay. So this is
16 all within Exhibit 11. So the second article within
17 Exhibit 11 is?

18 A. The response to this article.

19 Q. Okay. And the third article within
20 Exhibit 11?

21 A. This is vaginal -- these are different
22 papers, but they're not directly related to this one.

23 Q. That's okay. So these are all -- I guess
24 just to make sure just for purposes of the record,

1 Exhibit 11 contains additional medical literature that
2 you're relying on for your opinions; is that right?

3 A. Yes.

4 Q. Okay. We'll just leave it at that and then,
5 of course, if you need to refer to any of it during
6 your deposition --

7 A. And this is the paper that I was just
8 referring about the Bianchi-Ferraro on TVT-O and
9 TVT-S.

10 MR. DE LA CERDA: Okay. So I'll mark this
11 one separately as Exhibit 12.

12 MR. SNELL: Is that one in your report, do
13 you know?

14 THE WITNESS: No, but I refer to it on the
15 Garcia deposition.

16 (Plaintiff's Exhibit No. 12 was marked for
17 identification.)

18 MR. DE LA CERDA: For purposes of the
19 record, Exhibit 12 is a article entitled
20 "Randomized controlled trial comparing TVT-O and
21 TVT-S for the treatment of stress urinary
22 incontinence: 2-year results."

23 Is it okay if I clip --

24 A. Yes.

1 Q. (By Mr. De La Cerda) Just for now, and
2 then if you need to look at them, of course.

3 A. And I gave you a copy of my CV --

4 Q. Yes.

5 A. -- without my home address.

6 Q. Okay. I've got one here and if you like, I
7 can use this one for the record.

8 A. Yes, I just made it available to you in
9 case ...

10 MR. SNELL: Is that the same thing?

11 THE WITNESS: Yes, that's the one. The
12 Bianchi-Ferraro has been referred already on
13 this.

14 MR. SNELL: Footnote 117.

15 Q. (By Mr. De La Cerda) Okay. What I'm
16 going to do is I'm going to mark as Exhibit 13 to
17 your deposition your CV.

18 (Plaintiff's Exhibit No. 13 was marked for
19 identification.)

20 Q (By Mr. De La Cerda) So I'm marking as
21 Exhibit 13, that's your -- is that your current
22 curriculum vitae?

23 A. Yes.

24 Q. And is that, to the best of your knowledge,

1 current?

2 A. It is -- it is current.

3 Q. Okay. Anything else -- anything on it that
4 you know of that needs to be updated, corrected,
5 edited, anything like that?

6 A. On my report that I'm the principal
7 investigator at the Fibroid Registry research project,
8 that project was completed and closed.

9 Q. Okay. And is that the only thing on your CV
10 that you know of that would need to be corrected?

11 A. It was the only research project that was
12 open.

13 (Plaintiff's Exhibit No. 14 was marked for
14 identification.)

15 Q. (By Mr. De La Cerda) Okay. I'm also
16 marking as Exhibit 14 to your deposition your
17 Reliance List for the general report.

18 This is what I've received as your Reliance
19 List. Does that appear to be a true and correct copy
20 of it?

21 MR. SNELL: Is this Exhibit 14?

22 MR. DE LA CERDA: Yeah.

23 A. I don't see any discrepancies overall in
24 this list from what I have here.

1 Q. (By Mr. De La Cerda) Okay. Great. Now
2 I'm going to show you what I've marked as Exhibit 15
3 to your deposition.

4 (Plaintiff's Exhibit No. 15 was marked for
5 identification.)

6 Q. (By Mr. De La Cerda) Does this appear to
7 be a true and correct copy of your expert report,
8 your general expert report, on Gynemesh, Prolift and
9 Prosima?

10 A. This is accurate and correct.

11 (Plaintiff's Exhibit No. 16 was marked for
12 identification.)

13 Q (By Mr. De La Cerda) Okay. And now I'm
14 showing you what I've marked as Exhibit 16 to your
15 deposition. Does this appear to be a true and
16 correct copy of your general expert report on TVT
17 and TVT-O?

18 A. It is a correct copy.

19 MR. DE LA CERDA: We've been going now for
20 about an hour. Are you okay to continue or do
21 you want to take a break?

22 THE WITNESS: Let's take a bladder break and
23 we'll come back in five.

24 MR. DE LA CERDA: Sounds good.

1 (Thereupon, a recess was taken from
2 9:24 a.m. until 9:26 a.m., after which the
3 following proceedings were held:)

4 Q. (By Mr. De La Cerda) All right. Doctor,
5 we're back on the record.

6 When -- when was it that you were first
7 contacted regarding the general opinions that you have
8 as to these products that we're here today for?

9 A. For -- for the -- for the MDL, around
10 September. We spoke around September.

11 Q. September --

12 A. Last year.

13 Q. -- of last year, 2015?

14 A. Yes.

15 Q. And do you recall who you talked to first?

16 A. I -- I spoke to Burt.

17 Q. Okay. And was the topic discussed that you
18 would be providing general opinions as to these
19 specific products: TVT, TVT-O, Prosima, Prolift and
20 Gynemesh?

21 A. That's correct.

22 Q. And what was the scope of your assignment
23 for this particular -- for your opinions in this case,
24 to your understanding?

1 A. Yes, I understand the scope is to -- to
2 review the literature and -- and go over things that I
3 have read for -- throughout the years.

4 Q. Were there certain things that you were to
5 focus on within the context of your opinions?

6 A. The --

7 THE COURT REPORTER: I'm sorry, did you --

8 MR. SNELL: Objection, form. I just say
9 "form," but that means objection, form. I try to
10 cut down your typing on the record.

11 A. The randomized controlled trials concentrate
12 in the evidence.

13 Q. (By Mr. De La Cerda) What about internal
14 documents, was there any focus that you were to
15 place on the substance or the significance of
16 Ethicon's internal documents in forming your
17 opinions?

18 A. No. It's -- I have received -- just to be
19 accurate in my response, I received, probably a year
20 ago, internal documents, but not as part of this.

21 Q. Okay. So your focus really was and your
22 opinions here was to provide those opinions based on
23 literature as opposed to what was found in the
24 internal documents; is that fair?

1 MR. SNELL: Form.

2 A. Based on the -- on the evidence, on the
3 scientific evidence.

4 Q. (By Mr. De La Cerda) As opposed to the
5 internal documents; right?

6 A. The internal documents are not -- are not
7 included on -- on this review or -- because it's a
8 scientific review.

9 Q. I guess you haven't completed all -- well,
10 let me just ask.

11 Have you completed all of your work on this
12 case?

13 A. Yes. So far from my Reliance List and this
14 is -- this is the product.

15 Q. Do you currently have any further work
16 planned?

17 A. As -- as information may be required,
18 I'll -- I'll review the papers, I'll review scientific
19 literature, and everything that is coming up.

20 Q. So -- but as far as anything specific
21 planned, is there any additional -- is there any
22 additional task that you have planned? Other than,
23 you know, tomorrow we have depositions for the
24 case-specific, but other than the depositions coming

1 up tomorrow, are there any specific tasks that you
2 have planned relating to your opinions in this case?

3 A. No, this is -- this is my -- my product.

4 MR. SNELL: I'll make a note for the record.

5 As plaintiff's experts' depositions are coming
6 in, I know there are still depositions going on
7 today, tomorrow, we'll send those to him, and if
8 he has commentary or his opinions are changed,
9 then, obviously, I'll let you know.

10 Q. (By Mr. De La Cerda) How much have you
11 billed thus far for your general opinions involving
12 TVT, TVT-O, Prosima, Prolift and Gynemesh?

13 A. I have -- I have copies of the invoices that
14 I have submitted.

15 Is it okay if he has other -- other hours
16 from another case, or should I just say the number of
17 hours?

18 MR. SNELL: Let me see what you're talking
19 about. The invoices -- let me look at them real
20 quick.

21 MR. DE LA CERDA: Do you want to go off the
22 record for a second? Let's go off the record.

23 (Discussion held off the record.)

24 (Mr. Sparks entered the room.)

1 A. I can make copies again of it, but I did
2 prepare your invoices. My invoices to -- I put it in
3 a folder, they were neatly organized, the hours. I --
4 I just cannot find it, honestly cannot find it.

5 Q. (By Mr. De La Cerda) Okay. So what we'll
6 do is when you do find it, you'll agree to provide
7 that to us?

8 A. Absolutely.

9 Q. Okay. And so --

10 MR. SNELL: Why don't we save an exhibit
11 number on the record, and I'll produce that, but
12 I think he probably has a good idea as to how
13 many hours he spent.

14 MR. DE LA CERDA: Okay. So what I'm going
15 to do is, I'm reserving Exhibit 17 for the
16 invoices that Dr. Sepulveda has prepared
17 reflecting his work and his opinions for this
18 case.

19 (Plaintiff's Exhibit No. 17 was marked for
20 identification.)

21 Q. (By Mr. De La Cerda) First of all, do you
22 have an idea of approximately how many hours you've
23 spent preparing your opinions?

24 A. It's -- an approximate is about 120 hours.

1 Q. And your report mentions that you bill at
2 \$500 an hour; right?

3 A. Yes.

4 Q. And so was it -- was that rate the same for
5 all 120 hours that you performed --

6 A. Yes.

7 Q. And was -- do you know whether your invoice,
8 did it break down the tasks that you were performing,
9 did it break it down by product?

10 A. No, it's all MDL.

11 Q. Okay. Was it broken down by, for example,
12 reviewing documents, meeting -- meetings with defense
13 counsel, deposition time? Was it broken down in any
14 way like that?

15 A. No, it's just for MDL, all the time that
16 I've spent in putting -- putting together -- putting
17 the reports together, putting -- for all the different
18 products all into one MDL.

19 Q. Okay. So one block bill of 120 hours --

20 A. Right.

21 Q. -- approximately?

22 A. That's correct. Around -- approximately.

23 Q. Okay. Now, the types of tasks you would
24 perform in developing your opinions, what did those

1 include?

2 A. I have to write the report, I have to
3 proofread -- proofread it, and I update it with the --
4 with the Reliance List. I -- I do research and
5 whatever papers I -- I find that are relevant, I just
6 submit it and it gets added to the Reliance List.

7 Q. Okay.

8 A. I also -- I review the case specifics and
9 that included seven -- seven cases in which -- in
10 which depositions and medical records and summaries
11 were reviewed.

12 Q. Okay.

13 A. And then the time, getting together, getting
14 prepared for this.

15 Q. Anything else that you can think of?

16 A. That would be at a later time because we got
17 ready yesterday and the time today.

18 Q. Let's talk a little about what you just
19 mentioned. Does the 120 -- approximately 120 hours
20 that you mentioned, does that include all of your work
21 for the case-specific?

22 A. Yes.

23 Q. Okay. Do you know approximately how much
24 you spent -- how much time you spent as to each

1 case-specific report that you prepared?

2 A. I -- I probably spend about, just -- just a
3 rough, rough estimate, it's ten hours per each one,
4 each one of them.

5 Q. And do you know how many case-specific
6 reports you prepared?

7 A. Seven.

8 Q. Seven. Okay. I know these are rough
9 numbers here, but so seven case-specific reports at
10 about ten hours a piece, it's about 70 hours. So the
11 balance, the rest of that, would that be dedicated
12 towards your general opinions as to the products
13 involved here?

14 A. Yes.

15 Q. Okay. And you mentioned preparation for
16 your deposition. When is it that you prepared for
17 your deposition today?

18 A. Yesterday.

19 Q. And how long did you prepare?

20 A. We -- we spend eight, ten hours.

21 Q. And that's eight to ten hours that you spent
22 with Burt Snell?

23 A. Yes.

24 Q. Counsel for Ethicon; right?

1 A. Yes.

2 Q. Anybody else?

3 A. No.

4 Q. In your deposition preparation, you reviewed
5 documents; is that right?

6 A. Yes.

7 Q. Okay. Are those the documents that we have
8 here that we've marked today?

9 A. Yes.

10 Q. Okay.

11 A. And -- yeah, all this has been marked.

12 Q. Do you have any rough estimate of how much
13 more you anticipate billing before trial?

14 A. I -- I don't know when it's going to trial.
15 It's -- as they -- as they require, I just -- I'll
16 just review.

17 Q. Okay. Have you ever rendered an opinion in
18 litigation that was adverse to Johnson & Johnson or
19 Ethicon, Inc.?

20 A. No.

21 Q. Did you take any notes while you were doing
22 your preparation for your opinions?

23 A. I -- I'm a better highlighter than note
24 taker.

1 Q. Okay. I can never read my own notes, so I
2 don't -- I don't even take notes.

3 Okay. So you don't have any handwritten
4 notes regarding your opinions; is that right?

5 A. No, not on this.

6 Q. You mentioned the Reliance List. Was the
7 Reliance List originally prepared and provided to you
8 by Ethicon counsel?

9 A. It -- it was given by counsel, but I can
10 tell you that most of that Reliance List is trials
11 that are relevant enough that I have read it over
12 time.

13 Q. Okay. So then as you performed your own
14 research and found additional articles, you would then
15 submit them to Ethicon's counsel and then they would
16 get added to the Reliance List; is that right?

17 A. Right. That's -- whatever I want to add up,
18 I just submit.

19 Q. And that Reliance List is exhaustive other
20 than a few of the articles that we've identified
21 today, is that right, that have been marked?

22 A. Right, that's -- this is what includes it.

23 Q. Does your Reliance --

24 MR. SNELL: Could I make -- let me just make

1 a note on the record. He did bring another thumb
2 drive with a lot of Ethicon documents and
3 materials that he had in his possession and,
4 obviously, those would go and make up part and
5 parcel of his knowledge base as well.

6 MR. DE LA CERDA: I'm glad you brought that
7 up because I forgot to mark this thumb drive.

8 THE WITNESS: Can you just take a look
9 because I want to make sure I brought the right
10 thumb drive.

11 MR. SNELL: Okay.

12 THE WITNESS: I just dump it and I really
13 never review it.

14 I'm seeing one of the slides have the name
15 of a patient.

16 MR. SNELL: How do we deal with that?
17 because it looks like an image.

18 THE WITNESS: It's an image, yeah, it has a
19 name of a patient.

20 MR. SNELL: It has to be redacted.

21 THE WITNESS: Yeah.

22 MR. SNELL: Why don't we take it off the
23 thumb drive and we can figure out how to redact
24 it.

1 So Peter, just for your reference, we're
2 looking at the thumb drive Dr. Sepulveda brought.
3 There is a PowerPoint titled "Pillowing,
4 P-i-l-l-o-w-i-n-g, .ppxt, and it's got patient
5 identification information, so we'll take that
6 off the thumb drive and figure out how to redact
7 that. It looks like it's images. I can't even
8 read the name, but obviously once you open up the
9 file in realtime you can see it.

10 MR. DE LA CERDA: Okay. So for purposes of
11 the record, we're going to reserve --

12 Did we already reserve 17?

13 THE COURT REPORTER: Yes, for --

14 MR. SNELL: I think 17 was invoices.

15 MR. DE LA CERDA: Okay. So for purposes of
16 the record, we're going to reserve Exhibit No. 18
17 for a thumb drive that Dr. Sepulveda has brought
18 here today.

19 Q (By Mr. De La Cerda) And, for the record,
20 Dr. Sepulveda, can you tell us, generally speaking,
21 what is on the thumb drive that will be marked as
22 Exhibit 18?

23 A. It -- it has the presentations that I have
24 used for Prolift throughout the years, and it has the

1 presentation on Gynemesh, and it has the surgical
2 videos, and it has pictures of surgery that I have
3 included in those presentations.

4 MR. SNELL: Did you mention this product?

5 THE WITNESS: TVT-Secur.

6 Q. (By Mr. De La Cerda) And, apparently,
7 there are patient-identifying information on that
8 thumb drive and so that information is going to be
9 redacted and then the thumb drive will be provided
10 at a later date; correct?

11 A. There is one slide that has the patient ID.

12 MR. SNELL: What I was going to do is take
13 the file titled "Pillowing" with the
14 patient-protected information off the thumb
15 drive, put it on my local computer, and figure
16 out some time today if this law firm can redact
17 that.

18 MR. DE LA CERDA: That would be perfect.

19 MR. SNELL: But you'll have -- I mean, but
20 we'll mark the thumb drive, because I want a copy
21 of it, too.

22 MR. DE LA CERDA: Okay.

23 MR. SNELL: I'm just looking for -- is that
24 your data?

1 THE WITNESS: Yes, that's my own data.

2 MR. SNELL: Tell him about that.

3 A. I also included data of my own
4 complications.

5 Q. (By Mr. De La Cerda) Let's discuss them.
6 Actually, you know what, we'll come to that shortly.

7 MR. SNELL: Is that the same as the earlier
8 stuff without the patient identifying --

9 THE WITNESS: No, that's -- I put all the
10 files that have to do with it, so I had the files
11 that I use to prepare the presentation, and I
12 have the actual file slides with the
13 presentation.

14 MR. SNELL: Did you mention this product?

15 THE WITNESS: That's TVT-Secur.

16 MR. SNELL: This one?

17 THE WITNESS: And there's another
18 presentation on TVT-O.

19 MR. SNELL: Okay. Let me pull that one off.

20 Q. (By Mr. De La Cerda) Okay. And we'll
21 come back to the data on your own complications,
22 too. We'll discuss that in a moment.

23 Okay. Directing your attention back to
24 Exhibit 16 -- oh, wait. Is this report -- in

1 Exhibit 16 is your general report on TVT and TVT-O;
2 correct?

3 A. That's correct.

4 Q. Is this report a complete statement of all
5 general opinions that you'll express as to the TVT and
6 the TVT-O and the reasons for those opinions?

7 A. That report includes that, up to -- up to
8 today.

9 Q. So up to today, that report is a complete
10 statement of all general opinions you'll express as to
11 the TVT and TVT-O and the reasons for those opinions;
12 correct?

13 MR. SNELL: Form.

14 Go ahead.

15 A. That's correct.

16 Q. (By Mr. De La Cerda) Does this report,
17 your Reliance List, and the materials you've brought
18 today include all facts or data considered by you as
19 of today in forming your general opinions about the
20 TVT and the TVT-O?

21 A. Yes.

22 MR. SNELL: I took the one file off so you
23 can go ahead and mark that.

24 MR. DE LA CERDA: All right. So I am, for

1 the record, marking the thumb drive that we've
2 just discussed that Dr. Sepulveda brought as
3 Exhibit 18.

4 (Plaintiff's Exhibit No. 18 was marked for
5 identification.)

6 Q. (By Mr. De La Cerda) Okay. Now, Doctor,
7 directing your attention to Exhibit 15 and that's
8 your report on the Gynemesh, Prolift and Prosima;
9 correct?

10 A. Yes.

11 Q. Now, is this report a complete statement of
12 all general opinions you will express as to the
13 Gynemesh, Prolift, and Prosima and the reasons for
14 those opinions as of today?

15 A. Yes.

16 Q. And does this report, your Reliance List,
17 and the materials you brought today include all facts
18 or data considered by you in forming your general
19 opinions about the TVT and the TVT-O as of today?

20 A. Yes.

21 Q. Okay. Let's talk a little bit about your
22 practice. Where do you currently have privileges?

23 A. At South Miami Hospital, Baptist Hospital,
24 and South Miami Medical Arts Surgery Center.

1 Q. And do you currently perform surgeries to
2 correct stress urinary incontinence?

3 A. Yes.

4 Q. Now let's focus over the last ten years.

5 Over the last ten years, what surgeries have
6 you performed to correct stress urinary incontinence?

7 A. I have performed Burch procedures, TVT,
8 retropubic, and transobturator inside-out.

9 Q. Is that TVT-O?

10 A. That's correct, that's TVT-O.

11 And TVT-Secur, TVT-ABBREVO.

12 Q. Okay. Any others that you can recall
13 sitting here today?

14 A. I -- I recall doing 50 outside-in slings.

15 Q. Fifty outside-in slings.

16 A. Slings.

17 Q. Okay. Do you recall the brand of those?

18 A. That was from AMS.

19 Q. AMS. Is that the Monarc?

20 A. Monarc.

21 Q. You mentioned that you performed Burch as a
22 surgery to correct stress urinary incontinence. What
23 to you would be an indication to perform a Burch as
24 opposed to a synthetic midurethral sling?

1 A. I perform Burches rarely and I cannot -- I
2 cannot really remember off my head my last Burch.

3 Q. Why do you perform them rarely?

4 A. Because midurethral synthetic slings work
5 very well.

6 Q. Performing a synthetic midurethral sling,
7 it's a quicker procedure than a Burch; right?

8 A. It's just more than -- than quicker. It
9 performs -- short term and a long term, it performs
10 better than a Burch and it's -- that has been -- has
11 been my experience and that's what's supported by
12 data.

13 Q. Okay. So -- but are there any indications
14 to you -- when a patient comes into your office and
15 you're going to perform a surgery to correct the
16 stress urinary incontinence, what indications do you
17 say, I'm going to perform a Burch instead of a
18 synthetic midurethral sling?

19 A. My first option is a synthetic midurethral
20 sling and I counsel the patients on it. There may --
21 I may have a patient that may say I want a Burch for
22 one or other reason.

23 Q. Okay. So it's the patient making the
24 decision that they prefer a Burch over a synthetic

1 midurethral sling as opposed to you recommending the
2 Burch as the first option?

3 A. My patients are -- I have a well-educated
4 practice and they -- they actually may -- may bring
5 great questions about one or the other. My experience
6 is that they will follow my -- my recommendations.

7 Q. Right. Do you recall any instance where
8 you've recommended a Burch over a synthetic
9 midurethral sling?

10 A. There -- there was a time about when TVT
11 came in and for one or two years that we spoke in
12 those terms, but once randomized controlled trials
13 came in, it was -- I tell them that that's
14 basically -- is the best evidence that I have.

15 Q. Your understanding was that at least at one
16 time the Burch was the gold standard for correcting
17 stress urinary incontinence surgically; correct?

18 A. I -- I'm going to take exception to the
19 "gold standard" term, but there was a time in which
20 the Burch was the correct clinical -- clinical
21 practice.

22 Q. Would you use the gold standard term to
23 describe a synthetic midurethral sling?

24 A. I -- I just try to shy away from "gold

1 standard." I think that clinically, it's -- the
2 current clinical standard is probably a better -- a
3 better term.

4 Q. So a current clinical standard is a better
5 term to use than the term "gold standard"; right?

6 A. I -- I agree.

7 Q. Did you -- in the last ten years, have you
8 ever used slings using biologic materials?

9 A. I -- I don't know if it's within the last
10 ten years, but I -- I have used slings using
11 autologous, I have done slings using dermis cadaver
12 material. I may have used them one time posing, but
13 this is so -- so remote that -- that I cannot tell you
14 how many or which brand did I use.

15 Q. Do you remember any reasons why you would
16 have used those biologic slings?

17 A. If I had some- -- if I had someone that --
18 that was -- the person that comes to mind is my -- the
19 last pubovaginal sling and it was a smoker with --
20 with bad pressures in the urethra and I used the
21 pubovaginal sling in that patient at that time.

22 Q. What do you mean by "bad pressures"?

23 A. Very, very low pressures in the urethra.

24 Q. Okay.

1 A. It took very little for her to leak.

2 Q. Okay. And so why would it be that you would
3 use a biologic sling under those circumstances?

4 A. I use actually her own fascia and it -- it
5 was -- we didn't have anything -- anything -- we have
6 things that were synthetic but that were not
7 well-studied at that time.

8 Q. So this would have been, I assume, in either
9 the late '90s or early 2000s?

10 A. That's a wide range, yes.

11 Q. Okay. You mentioned TVT Retropubic, TVT-O,
12 TVT-S, and TVT-ABBREVO that you performed in the last
13 ten years.

14 Do you know approximately how many of each
15 of those you performed?

16 A. I -- I counted about -- at one time it was
17 about 300 slings a year.

18 Q. Okay. And do you know what the breakdown
19 was of those 300 per year as to the TVT Retropubic,
20 TVT-O, TVT-S, and TVT-ABBREVO?

21 A. It was an evolution from TVT Retropubic to
22 TVT-O and to TVT-Secur and then ABBREVO.

23 Q. Okay. So over -- over time, you might --
24 you know, you started with a TVT Retropubic, then

1 you -- then you preferred the TVT-O, so you would
2 switch to that; is that right?

3 A. Yes.

4 Q. And then you would prefer the TVT-S and you
5 would switch to that?

6 A. Yes.

7 Q. And then later you preferred the TVT-ABBREVO
8 and switched to that; is that right?

9 A. Right.

10 Q. Do you still perform TVT-Os, though, or do
11 you just kind of stick with the TVT-ABBREVO?

12 A. I do it at the surgery center so we choose
13 one. And since I do most of the slings, and I'm the
14 medical director for the surgery center, I decide I'm
15 going to use this or that one. We still have TVT-O on
16 the shelf, but we -- we use TVT -- TVT-ABBREVO.

17 Q. Okay. Why would you prefer a TVT-ABBREVO
18 over a TVT-O?

19 MR. SNELL: Form.

20 A. I have not found a scientific -- a
21 scientific reason for it except for the fact that --
22 that it's the most recent product and it's -- it's a
23 12-centimeter sling instead of a longer sling.

24 Q. (By Mr. De La Cerda) What's the

1 significance of it being a shorter sling as opposed
2 to a longer sling?

3 A. It's -- I decided that if I can do it with
4 12 centimeters, I'm not going to use 19 centimeters
5 when the evidence is good in my practice.

6 Q. Is -- you agree with the general theory that
7 less foreign body is better when it comes to these
8 types of procedures?

9 MR. SNELL: Form.

10 A. No, I think that there are physicians that
11 have a level of comfort with TVT-O or, for that sake,
12 with TVT Retropubic, and that being with a
13 5-millimeter needle, a 3-millimeter needle.

14 Each physician has his own level of comfort
15 and they're going to use what works well for them. I
16 have not found any scientific evidence that points out
17 to one being better than the other based on that.

18 Q. (By Mr. De La Cerda) What about the
19 general -- do you agree with the general
20 proposition, though, that more foreign body will
21 cause more foreign body reaction within the human
22 body?

23 MR. SNELL: Objection, asked and answered.

24 A. It assumes -- it assumes that there's -- the

1 term "foreign body" probably is the same -- in the
2 same area as "gold standard." They're -- they're very
3 wide, very unscientific. They -- in terms of the
4 material that you leave in the area, if a physician
5 would come and ask me, "Do you think I should do this
6 because it leaves less material," I could not tell him
7 with certainty, "Yes, you definitely need to move from
8 one to the other." I have no evidence to support
9 that.

10 Q. (By Mr. De La Cerda) And so, ultimately,
11 you switched to the TVT-ABBREVO just because of your
12 personal experience with it?

13 A. It's easier -- easier to keep on the shelf,
14 the TVT-ABBREVO. If -- I guess, right now, if there
15 would be -- there would be only TVT-0, I would be
16 perfectly comfortable with it.

17 Q. Okay. Do you know whether TVT-ABBREVO comes
18 in laser cut or mechanically cut?

19 A. Laser -- it comes in laser cut.

20 Q. TVT-ABBREVO is only laser cut; right?

21 A. Right.

22 Q. Do you know whether the Burch procedure is
23 still taught in medical school?

24 A. I don't know.

1 Q. Is the Burch procedure within the standard
2 of care?

3 A. I think that for a physician that wants to
4 do Burch procedures, that may apply.

5 Q. You wouldn't criticize another doctor for
6 doing a Burch procedure over a synthetic midurethral
7 sling; right?

8 A. I would not be -- be critical. I can share
9 it, the evidence, but there's -- there's no reason for
10 being critical over the Burch procedure.

11 Q. Are pubovaginal slings using native tissue
12 still taught in medical school, to your knowledge?

13 A. No, I don't think they are taught -- I
14 probably don't know, but I don't think they are.

15 Q. And if a physician performed a pubovaginal
16 sling using native tissue, would you criticize him or
17 her for doing that?

18 A. That's -- I have to say that's an excellent
19 question because it's -- it probably is the procedure
20 that would prompt me to say, "Listen, you need to
21 reevaluate on how you're taking care of these
22 patients," because that can be a morbid procedure.

23 Q. So that one is a little more borderline for
24 you?

1 A. Yes.

2 Q. Yeah.

3 A. And I can -- I can do that well -- I want to
4 think that I can do it well because I did it well at
5 one time, it's just that it's -- in terms of morbidity
6 and seroma and wound complications and obstruction,
7 it's -- it's a different -- different surgery.

8 Q. Would you consider it to be within the
9 standard of care or no?

10 A. I -- I think that in certain areas, probably
11 if that's -- we go to areas where they don't have what
12 we have, that could be considered standard of care.

13 Q. You've never done a study to determine what
14 percentage of medical schools are teaching Burch or
15 pubovaginal slings using native tissue; right?

16 A. No, I don't know that.

17 Q. In your career, how many revision or
18 excision surgeries involving synthetic midurethral
19 slings have you performed?

20 A. I -- I think I have done three. I may have
21 done more than that. Just in my mind it's -- it's
22 infrequent enough that I actually -- one of the
23 presentations on the thumb drive is me excising a
24 sling, the pictures. That's how infrequent it is.

1 Q. So to -- I'm sorry, I didn't want to cut you
2 off.

3 A. So I actually consent to the patient and I
4 said, "This is unusual." I consent to the patient to
5 have it removed.

6 Q. Okay. So to your recollection, you've done
7 three revision or excision surgeries involving
8 synthetic midurethral slings?

9 A. I don't want to come into a fault -- faulty
10 memory, but I can recall about three.

11 Q. Okay. Of those three, how many were you
12 able to remove the entire sling?

13 MR. SNELL: Form.

14 A. On the -- it's probably two of them, the
15 entire -- the entire sling being up -- up to the
16 descending pubic ramus in that area. I remove the
17 entirety of it.

18 Q. (By Mr. De La Cerda) And so that was --
19 that's the portion that is actually under the
20 urethra but not the portion that goes into the pubic
21 ramus; is that right?

22 A. The portion that gets about -- to about
23 1 centimeter from the obturator internus muscle.

24 Q. Okay.

1 A. So anything that is beyond the obturator
2 internus muscle, I -- I stay away from that.

3 Q. Is that because the risk outweighs the
4 benefit of removing that mesh that's beyond the
5 obturator internus muscle?

6 A. It's -- there are three factors to it.

7 Q. Okay.

8 A. The first one is that the orientation of the
9 tape is very misleading to the surgeon. It comes
10 forward to you and many surgeons, if they're
11 inexperienced, they'll keep digging into the area and
12 cause harm to the lateral side. That's one -- one of
13 the other reasons.

14 The second reason is that I haven't found
15 any -- anything convincing, and I keep looking for
16 anything that has been written about excising that --
17 that portion of the -- of the tape.

18 And number three is that most of the time,
19 2, 3 percent of the time that we're going to revise a
20 sling for avoiding this function, it makes no -- no --
21 there's no justification, I should say, there's no
22 justification to go beyond that area.

23 Q. Okay.

24 A. Beyond the area within the obturator

1 internus muscle.

2 Q. And of these three revisionary excisions --
3 let me first clarify.

4 Are the three revision or excision
5 surgeries, are they all three excision surgeries or
6 revision or both? How would you characterize them?

7 A. They are excisions. I was speaking about
8 removing the whole thing.

9 Q. So those three were excision surgeries.
10 Were those three patients, patients you had
11 implanted the sling or someone else?

12 A. I had one that I implanted the sling and two
13 that came from -- came referred to me.

14 Q. Okay. So to your recollection, and you've
15 implanted 300 synthetic midurethral slings for the
16 last -- per year for approximately the last ten years;
17 right?

18 A. Lately, they're -- the number of slings is
19 less.

20 Q. Okay. So would a fair estimation be that
21 somewhere between 2- and 3,000 synthetic midurethral
22 slings is what you've implanted?

23 A. Yes.

24 Q. Okay. In the last ten years; right?

1 A. Yeah, over the last ten years, yeah, that
2 would be accurate.

3 Q. And of those 2- to 3,000 synthetic
4 midurethral slings, your testimony is that you've only
5 excised one of -- you've only, personally, excised one
6 of the slings that you've put in; is that right?

7 A. Yes. That I remember, one. I may -- may
8 have taken a segment or a fiber from another sling
9 that I might have placed. I haven't kept track of it
10 because the reality is that it's extremely rare. I'm
11 going to tell you, what happens most of the time is
12 you put the sling, the patient comes in, she's dry,
13 she's happy, she moves on.

14 Q. What were the reasons why you performed the
15 three excision surgeries that you can recall?

16 A. One of them was -- was just a tight sling on
17 the patient. A young patient with a tight sling and
18 she was having difficulty urinating.

19 I recall one -- another one was someone with
20 a sling that was not a mid-urethra, it was higher.
21 The sling was placed higher than the urethra and it
22 wasn't working and I took that one and put one in the
23 urethra.

24 Q. Any other reason that you can recall?

1 A. No. I had -- I had one that came in because
2 she had -- she had pain on the area of the insertion
3 of the sling.

4 Q. Okay. So you had one with pain -- have you
5 ever removed a synthetic midurethral sling because of
6 an erosion?

7 A. Yes, I have. I have removed that erosion
8 and I actually had one that I didn't put in -- put in
9 those three. Now I recall one that she broke the
10 incision and when I saw the patient coming on the
11 third week, on the third week, I asked her, "How is it
12 working?" She said, "Well, it's working."

13 And I examine her and she -- she had an
14 exposure on the -- on the sling. She was honest --
15 honest enough to tell me, "Doctor, I was at home
16 eating, I was choking on food and I threw myself over
17 a chair and I felt -- I felt something." So she broke
18 the incision line, and I saw it and I said, "Okay,
19 well, I'll -- I recommend that you have this removed."

20 Q. So is that the -- is your testimony that's
21 the only exposure -- or that circumstance you just
22 mentioned, is that the only exposure where erosion of
23 a synthetic midurethral slings that you had to treat?

24 A. No, I had a couple of exposures in the -- in

1 the past, but it's something that either you give
2 estrogen or you just take the fibers with a tenotomy
3 scissors, which are using in reconstructive surgery,
4 actually they're used in the eye and they have --
5 they're just perfect for this.

6 Q. I guess my crude understanding of that is
7 it's like an in-office trimming of the exposed mesh;
8 is that right?

9 A. It's -- you may have a few segments. In
10 other words, you have not seen the whole incision open
11 up.

12 Q. Okay.

13 A. And I -- I do remember a long time ago I saw
14 a patient with a segment on one side. That's the only
15 one I remember that the exposure was not in the
16 midline on the incision. And that patient, I tried to
17 convince her to let me take it and she said, "No,
18 you're not going to take anything because it's not
19 bothering me."

20 Q. So these are -- these are done -- this
21 procedure you just mentioned, this trimming of the
22 sling is done in-office, not under general anesthesia
23 in surgery; right?

24 A. Right.

1 Q. Have you ever performed an excision surgery
2 or revision surgery because the patient was suffering
3 from dyspareunia?

4 MR. SNELL: Form.

5 A. I -- I did one, same one that was having --

6 Q. (By Mr. De La Cerda) Pain?

7 A. -- the pain, yeah.

8 Q. Got it. Okay.

9 All right. The TVTs and the TVT-Os that
10 you've placed, those have involved -- or have been
11 mesh that is mechanically cut mesh and mesh that is
12 laser cut mesh; right?

13 A. Both.

14 Q. Did that have anything to do with the time
15 period in which you were implanting it or do you
16 just -- did you stock both or what did that have to
17 do -- any factors that that had to do with?

18 A. No, I did not have any specific reason to
19 choose one over the other.

20 Q. Okay. Over the last ten years you performed
21 surgeries to correct pelvic organ prolapse; right?

22 A. Yes.

23 Q. What types of surgeries have you performed?

24 A. I have performed anterior repairs, posterior

1 repairs, enterocele repairs, iliococcygeal suspension,
2 sacral spinous ligamentous suspension, abdominal
3 sacrocolpopexies, robotic sacrocolpopexies, Prolift,
4 graft reinforced repair with biologicals, augmented
5 repairs with Gynemesh, perineoplasty.

6 I think I have mentioned probably all of
7 them.

8 Q. The anterior and posterior repairs, did
9 those include colporrhaphies?

10 A. Yes.

11 Q. Are those synonymous or --

12 A. Pretty much, yes.

13 Q. Okay. Now, all the repairs that you just
14 mentioned, those are all within the standard of care;
15 right?

16 A. Yes.

17 Q. Is implanting transvaginal mesh -- strike
18 that.

19 Is implanting synthetic polypropylene mesh
20 transvaginally still within the standard of care?

21 MR. SNELL: Form.

22 A. It's still within the standard of care if it
23 will have the product available.

24 Q. (By Mr. De La Cerda) As of now, from the

1 Ethicon products, Gynemesh is still available;
2 right?

3 A. Gynemesh is still available.

4 Q. And do you -- is it your opinion that it's
5 still within the standard of care to implant Gynemesh
6 transvaginally for the treatment of pelvic organ
7 prolapse?

8 A. I believe it changed, the actual indication
9 or clearance. I may have read that.

10 Q. So the indication now is to use it for
11 abdominal sacrocolpopexies; right?

12 A. Yes.

13 Q. So is it within the standard of care,
14 though, to implant Gynemesh -- I'm talking about
15 today -- so is it as of today within the standard of
16 care to implant Gynemesh transvaginally for the
17 treatment of pelvic organ prolapse?

18 A. Not -- not today.

19 Q. Okay.

20 A. Based on what I just stated.

21 Q. Okay. What was -- what was for you an
22 indication in the past to implant synthetic mesh
23 transvaginally for the treatment of pelvic organ
24 prolapse as opposed to doing one of the other non-mesh

1 procedures that you've mentioned?

2 A. I -- I came to the clinical appreciation
3 that patients that have had a hysterectomy, patients
4 that have had recurrent prolapse, patients that had a
5 high degree of exertion, and patients that have a
6 recurrent compartment or a contralateral compartment
7 defect, those patients benefit from it.

8 I -- that's the general. I knew that I had
9 patients that have -- I had one shot to take to the
10 operating room and I -- for whatever reason, and those
11 are the most difficult ones because they were more
12 complicated, but on the other side, you wanted to give
13 her the durability of the repair.

14 That's -- that's in general what I -- what I
15 use when I counsel someone on the -- on the use of
16 this synthetic graft. We started -- we started
17 reading then, around the time that we had Gynemesh,
18 more and more about durability and the repairs,
19 specifically for those apical -- apical defects, so it
20 became very attractive to treat patients on the
21 apical, with apical defects, and when we didn't have
22 to do an incision.

23 Q. Have you ever performed revision or excision
24 surgeries involving synthetic polypropylene

1 transvaginal mesh for pelvic organ prolapse?

2 A. Yes, I have.

3 Q. And how many have you done of that?

4 A. I look at those and they may be in the -- in
5 the 10, 20, may be right -- right there based on what
6 I saw the last time.

7 Q. So approximately 10 to 20 in your career
8 revision or excision surgeries involving synthetic
9 polypropylene transvaginal mesh?

10 A. That's -- that's a ballpark figure, yes.
11 That's a very general figure.

12 Q. And of those 10 to 20, how many were you
13 able to remove the entire mesh device?

14 MR. SNELL: Form, foundation.

15 A. In most of them -- most of them you can
16 dissect the space -- the same space where you place it
17 and you can -- you can remove it. It's -- if you have
18 it in the muscle, obviously that's -- I already stated
19 that there is no benefit of doing that. But if you
20 dissect that area, you bring it up and you
21 hydrodissect your segments, you're -- you can remove
22 most of it.

23 Q. (By Mr. De La Cerda) Have you ever
24 performed a revision or excision surgery because the

1 patient was reporting pain and this is, again, I'm
2 talking about patients with transvaginal mesh for
3 pelvic organ prolapse?

4 A. You know, pain -- pain is rare after this
5 kind of repair. What most frequently happen is that
6 you would get in to have -- to remove an exposure, and
7 then you end up -- you ended up removing more than
8 what you thought you were going to remove because you
9 had the plane and you were just dissecting the area
10 and remove it. Then you ended up reinforcing the area
11 with sutures.

12 There are times in which I -- I -- I say I
13 have to do something to support it and it becomes such
14 a subjective thing that I wish I could have explained
15 this not now, but even when doctors would ask me the
16 same questions and -- and be accurate and precise
17 about it, but no, it's a general -- it's a general
18 idea. What I'm explaining now is a general idea of
19 what happens in the operating room when you're going
20 to remove it. So you start small, but you start
21 extending yourself on the dissection.

22 Q. So of the 10 to 20, though, how many of
23 those did you remove for the reason of that they
24 had -- they were experiencing pain?

1 A. It's -- I think it's rare. I can't give you
2 a specific number without -- okay, I want to be
3 accurate and precise, but it was rare. The most
4 recurring reason was an exposure.

5 Q. Okay. And did they report exposure with
6 pain or no?

7 A. No. No. They -- most frequent complaint
8 with the exposure was vaginal discharge.

9 Q. So were the 10 to 20 excision surgeries,
10 were those primarily because of exposures?

11 A. It's -- it's -- mostly exposure and
12 symptomatic exposures, exposures in which you saw
13 granulation tissue.

14 Q. Of granulation tissue, okay.

15 Were any of the excision procedures
16 performed specifically because of dyspareunia?

17 A. No, I don't remember anyone specific on
18 dyspareunia. I remember taking one Prolift that was
19 dyspareunia and pain.

20 Q. Have you ever -- have you ever had a patient
21 come to you reporting dyspareunia or pain after having
22 had a transvaginal mesh or pelvic organ prolapse where
23 you believed it was the transvaginal mesh causing the
24 pain or dyspareunia?

1 A. No. Most of the patients that we see with
2 dyspareunia, in a busy vaginal surgery practice, is
3 without mesh.

4 Q. So you've never had that happen where you
5 believed the dyspareunia was being caused by the
6 transvaginal mesh; right?

7 A. By -- specifically by transvaginal mesh, no.

8 Q. Same question for the -- I don't know if I
9 asked you for the slings, but have you ever had a
10 patient come to you reporting pelvic pain or
11 dyspareunia after having had a synthetic midurethral
12 sling where you believed that it was the sling causing
13 that pain or dyspareunia?

14 A. No, I -- I saw one sling that was low enough
15 that I -- it could -- that could have been the source
16 of dyspareunia.

17 Q. Okay. And I guess really you're thinking
18 it's more the positioning of the sling as opposed to
19 the actual sling; right?

20 A. Yes.

21 Q. Okay. How many Gynemesh PS's have you
22 implanted in your practice, in your career?

23 A. Over a hundred.

24 Q. And how many Prolifts have you implanted in

1 your career?

2 A. Definitely more than 100.

3 Q. Between 100 and 200?

4 A. Easily.

5 Q. How many Prosimas have you implanted in your
6 career?

7 A. I did about 50.

8 Q. Okay. Turning -- we've now been going
9 another hour. Would you like to take a break?

10 A. Yes, just quick as before.

11 (Thereupon, a recess was taken from
12 10:21 a.m. until 10:29 a.m., after which the
13 following proceedings were held:)

14 Q. (By Mr. De La Cerda) Okay. We are back
15 on the record.

16 Doctor, I wanted to direct your attention
17 back to your CV, please, which is Exhibit 13. Just a
18 couple quick things. If you'll turn to the fourth
19 page, the section which is "Courses Presented."

20 A. Yes.

21 Q. The entities that I've seen -- well, the
22 entities that are mentioned within this section where
23 you've presented a course, the only entities I've seen
24 mentioned are Johnson & Johnson, Ethicon Endo and

1 Ethicon.

2 Are there any other entities mentioned here
3 or no?

4 A. No, I never worked outside of Ethicon for
5 any another company.

6 Q. Then under "Research Experience," which is,
7 I guess, a couple pages later, is there -- do you have
8 listed here any research on transvaginal polypropylene
9 midurethral slings or transvaginal polypropylene
10 pelvic organ prolapse mesh?

11 A. No, I did not do research on transvaginal
12 sling. I rely on the randomized control trials.

13 Q. And then under "Presentations and
14 Publications as Author or Coauthor," I didn't see any
15 presentations or publications that involve
16 transvaginal polypropylene midurethral slings or
17 transvaginal polypropylene mesh for pelvic organ
18 prolapse; is that right?

19 A. Yes, I did not -- I did not publish on
20 transvaginal slings.

21 Q. We can set that aside for a second.

22 Okay. You're not a biomedical engineer;
23 correct?

24 A. I -- I have a very good understanding of

1 biomedical engineering.

2 Q. Okay. Would you consider yourself a
3 biomedical engineer?

4 A. I do not get compensated for doing
5 biomedical engineering.

6 Q. Okay.

7 A. And I did not graduate from -- with a degree
8 of biomedical engineering. I do -- I do understand
9 biomedical engineering well.

10 Q. I saw that you brought some books here that
11 would relate to that, I believe. What is it that
12 would provide the basis for your belief that you have
13 expertise in biomedical engineering?

14 A. I have devoted years to understand it, to
15 read about it beyond what any other physician that I
16 ever met have done.

17 Q. Anything else?

18 A. I have studied, I have spoken to biomedical
19 engineers, but specifically it's a passion and a
20 dedication that I have had to understand it.

21 Q. Would you consider yourself an expert on the
22 design of medical devices?

23 A. It goes right along with the biomedical
24 engineering, with the surgical expertise that allows

1 me to see what -- what can save in terms of efficiency
2 in the operating room, what can I do better for my
3 patients. That's what I use this for. This allows me
4 to understand the design better.

5 Q. Have you ever, personally, designed a
6 medical device?

7 A. I -- not -- not a medical device, but I have
8 my own set of needles that I actually had made.

9 Q. What were those needles for?

10 A. For -- to approach the deep space in the
11 pelvis.

12 Q. Were those used in connection with
13 implanting mesh at all?

14 A. No, I use them for sutures.

15 Q. Okay. Have you ever been involved in the
16 design of a medical device?

17 A. I -- I did give input to the design. It was
18 not -- it was not my own patent.

19 Q. And what device was that?

20 A. Staplers for -- for -- staplers, a
21 retractor, again, a circumferential needle.

22 Q. And these are all devices that are used in
23 connection with surgery?

24 A. Yes.

1 Q. Were you ever designed -- were you ever
2 involved in the design of any transvaginal mesh
3 devices?

4 A. Not in the devices of the ones that I use.

5 Q. Do you have any patents on medical devices?

6 A. No.

7 Q. Do you know what the standard is for a --
8 that a manufacturer must follow in designing mesh
9 products?

10 A. I'm -- I became very familiarized with --
11 when I was with Ethicon by my own inquiries.

12 Q. What standards did Ethicon employ in the
13 design of its mesh products?

14 A. It's -- it was from the initiation, from
15 what they had an idea of what the device was, what the
16 need was, and then there were -- I know there was a
17 structure for research and development with the
18 running of different -- different trials at different
19 levels. And I get that information and submit it,
20 along with other information that I was -- in which --
21 that had nothing to do with surgery, but cytotoxicity,
22 paragenicity assays, cell cultures assays, and all
23 this information submitted to the FDA, who would then
24 review it and -- and within its own division for the

1 device and then get back to them.

2 Q. Do you know what a manufacturer researches
3 before a product is designed or released?

4 MR. SNELL: Form, overbroad.

5 A. The --

6 Q. (By Mr. De La Cerda) Let's take it a
7 little more specific to the mesh products.

8 What did -- what, to your knowledge, did
9 Ethicon research in regard to its mesh products before
10 they were released?

11 A. I know that they -- they went through their
12 suture -- suture research and -- and I know that they
13 did experiments short term and long term with sutures.

14 I know that there was an opinion acquired
15 from the field on the use of different sutures. Then
16 there was a -- there was a use on the type of mesh
17 that was used for prolapse on the different types of
18 meshes. That wasn't done in the United States, that
19 was done in France.

20 And there was also -- the materials were
21 even evaluated in the same -- in the same way that
22 sutures are evaluated, but also in the operating room.
23 I'm aware of that one, too.

24 I'm aware that the needles and the approach

1 that was used was evaluated by them before it was even
2 used in the United States. And I know the packaging,
3 the packaging was evaluated. I was able to see how
4 they design the package for the operating room.

5 So all those lines never got to the place
6 where they actually do the knitting of the material,
7 never -- never got to see that, but I know there was a
8 facility for that.

9 So there was a step of -- actually quite an
10 elaborate chain that ended up giving the product.

11 Q. Do you know what types of experts were
12 involved in the design of Ethicon's mesh products?

13 A. I spoke to materials engineers. I actually
14 enjoy very much when I interacted with one of the
15 biomechanical engineers over there that had a doctor's
16 degree on biomaterials and I actually -- and I enjoyed
17 that. I look at different -- they asked me for
18 different types of materials. We look at -- they got
19 my input on fibers.

20 I know that there was another group in
21 France that was using those materials. One thing that
22 I observed is that it would not just go with just one
23 opinion, it was a consensus of different surgeons and
24 different -- different settings.

1 Q. Do you remember the names of any of the
2 folks that you interacted with on those issues?

3 A. I can't -- I can't remember because it's
4 over -- over five years and, you know, it's -- it
5 wasn't a friendship that would continue beyond that.
6 It was a work relationship.

7 Q. Do you know what a "design history file" is?

8 A. No.

9 Q. Are you familiar with industry standards
10 that govern medical device design?

11 A. I read at one time, I read that. I read
12 about ISO testing. I read about ISO testing. I read
13 about the different toxicity assays and, actually, at
14 one time I even may have read about the testing that
15 was done for -- for meshes that was using sutures,
16 i.e., I actually research it and read about it.

17 Q. Anything else that you can recall?

18 A. No.

19 Q. I'm sorry, is that --

20 A. I'm sorry. Not at this moment.

21 Q. Are you familiar with regulatory standards
22 that govern medical devices?

23 A. I became -- I became aware of the regulatory
24 standards. I knew about the classifications of

1 devices. I had an idea of the classification of the
2 devices and I had an idea, because I use other types
3 of -- of devices that have nothing to do with mesh.

4 Q. What's your understanding of the
5 classifications of devices?

6 A. I knew that heart -- heart monitors and
7 nerve stimulators and intermittent nerve stimulator
8 had a different classification than our meshes had and
9 that surgical instruments would have and that sutures
10 would have. You can -- you can just open -- you go to
11 the operating room and get into one of the boxes of
12 the sutures and you can pull that paper that gives all
13 these different things about the sutures. So it's --
14 I knew I had -- I had an idea of the different -- at
15 least three classifications that were used.

16 Q. Some requiring testing before they go out on
17 the market, some perhaps not; right?

18 MR. SNELL: Form.

19 A. Some methods -- some methods did require
20 different type -- different types of testing,
21 different -- each one had different requirements.

22 Q. (By Mr. De La Cerda) Do you know how
23 pelvic organ prolapse, transvaginal synthetic
24 polypropylene mesh is currently classified?

1 A. It's -- I read, recently, the classification
2 for prolapse meshes and for -- they went up to
3 Class 3.

4 Q. And what does that mean to your
5 understanding?

6 A. They are classified as high-risk devices.

7 Q. Do you agree with that?

8 A. I -- I'll -- I agree with the approval that
9 the FDA has and I'm not going to challenge the FDA or
10 their panel on that one.

11 Q. Fair enough. Would you -- are you an expert
12 in polymer chemistry?

13 A. I -- I don't design polymer chemicals. I do
14 understand certain -- the polymers that are used in my
15 specialty.

16 Q. And what polymers would those be?

17 A. When it comes down to polymers used in my
18 specialty, it's polypropylene.

19 Q. Are you an expert in surgical pathology?

20 A. That -- that's an average over the last 25
21 years, I do look at slides.

22 Q. And that would -- that would be the basis
23 for you stating that you had expertise in surgical
24 pathology; is that right?

1 A. I think that everyone that is a surgeon
2 needs to have an expertise in surgical pathology.

3 Q. Okay. So that would be your basis for
4 saying that; right?

5 A. That's correct.

6 Q. I didn't ask you this. What would be your
7 basis for saying you have expertise in polymer
8 chemistry, is it your experience?

9 A. My experience and what I read, the time that
10 I devote, the time that I have devoted over the years
11 to look at sutures and specifically polypropylene.

12 Q. Have you ever personally done chemical tests
13 to determine if polypropylene mesh degrades?

14 A. I have not personally done -- done that
15 testing. I did -- I did -- I have -- I read about it
16 and have considered that hypothesis.

17 Q. Have you ever done a microscopic analysis of
18 explanted polypropylene mesh to determine if the mesh
19 degraded personally?

20 A. Not -- not with the purpose of degradation
21 because I still -- I still looking for what -- what
22 does degradation really mean in the pathology
23 specimen.

24 Q. Okay. I'm going to shift gears a little

1 bit.

2 Would it be fair to say that before a
3 physician decides to utilize a transvaginal
4 polypropylene mesh or sling to treat a patient, that
5 it's necessary for the physician to warn the patient
6 of all known side effects of the product, including
7 severe ones?

8 MR. SNELL: Objection, form, speculation.

9 A. I think that before any -- any surgery,
10 there has to be -- there has to be a full
11 understanding of the -- as part of the informed
12 consent. And when -- when that's happening, there --
13 there are factors that are going to play into it.

14 Yes, ideally, we should be able to clear our
15 patients and get -- get a full understanding of it.
16 There are times in which the patient cannot understand
17 it and we have to find, as physicians and surgeons, a
18 way to get them through the most relevance. But that
19 including -- includes surgery with or without mesh.

20 Q. (By Mr. De La Cerda) Okay. So do you
21 think that all the known side effects, including
22 severe ones, should be disclosed to patients?

23 MR. SNELL: Same objection, form.

24 A. It's all known -- not only side effects, but

1 essentially what -- what could happen that is within
2 my control that is -- and what's not in my control and
3 patients appreciate that we do that.

4 Q. (By Mr. De La Cerda) A physician should
5 warn his patient -- his or her patient of
6 characteristics of the transvaginal mesh or sling
7 product that can significantly increase their risk
8 of severe complications; correct?

9 MR. SNELL: Form, foundation.

10 A. On that counseling, the counseling should
11 involve what has been tested. In other words, the
12 last thing that you want as a patient is to be
13 overwhelmed by just a wealth of data that is not
14 clinically relevant, and we -- we have studies that
15 actually address that.

16 Q. (By Mr. De La Cerda) So I think we might
17 be getting to something there. If -- if a
18 characteristic of a transvaginal mesh or sling
19 product is clinically relevant, should that be
20 disclosed to a patient during the informed consent
21 process?

22 MR. SNELL: Same objection, foundation.

23 A. The informed consent addresses that.

24 Q. (By Mr. De La Cerda) So is that a "yes"?

1 A. That would be in general a yes within --
2 within the parameters of that conversation between the
3 physician and the -- and the patient. So it would be
4 a yes with a condition that with knowing that that's
5 very unique. That's a very unique interaction.

6 Q. Okay. Do you agree that a physician has a
7 duty to inform his or her patients of the material
8 risks associated with a transvaginal mesh or sling
9 product before it's implanted in the patient?

10 MR. SNELL: Form, foundation, overbroad.

11 A. I -- I -- my opinion is that the patient
12 should be informed not only of -- of the mesh, but
13 if -- if surgery is being done with sutures, the
14 patient should know that, too.

15 Q. (By Mr. De La Cerda) I mean, what I'm
16 trying to do is use different terms for the risks or
17 complications and in this one I'm using material
18 risks associated with transvaginal mesh or sling
19 product. Do you think that material risks should be
20 disclosed to the patient?

21 MR. SNELL: Same objection, vague,
22 immaterial.

23 A. Just to clarify, are you talking about the
24 material or the material risk?

1 Q. (By Mr. De La Cerda) That's a good
2 question.

3 Material, that term I'm using -- because
4 there's different ways that we've seen risks and
5 complications associated with mesh products described
6 by physicians. Sometimes they describe those risks as
7 material risks, not as the material polypropylene, but
8 as being relevant risks.

9 A. Oh.

10 Q. They're using that word.

11 A. I understand.

12 Q. That's a good question. Some doctors have
13 used the term "material risk, "Yeah, I disclose it if
14 it was a material risk."

15 Now with that explanation, do you believe
16 that material risks associated with these products
17 should be disclosed during the informed consent
18 process?

19 MR. SNELL: Same objection.

20 A. The material risk associated with the whole
21 extent of the procedure should be -- should be
22 disclosed.

23 Q. (By Mr. De La Cerda) Okay. You mentioned
24 the term "clinically relevant." Is that the same

1 thing as clinically significant?

2 A. Um, clinically relevant is statistically
3 significant.

4 Q. Could you explain what that means, what your
5 understanding is of that?

6 A. It's -- with the best level of evidence that
7 we have for what we're doing, explain to the patient
8 this is -- we're going to translate it from the
9 statistically significant to what's common and what's
10 relevant in the surgery.

11 Q. Okay. I'm going to try and ask this
12 properly.

13 Do you agree that a physician should warn
14 his or her patients of risks or complications
15 associated with the transvaginal mesh or sling
16 products that are clinically relevant or statistically
17 significant?

18 MR. SNELL: Form.

19 A. For the whole extent of the procedure.

20 Q. (By Mr. De La Cerda) Including the
21 products, though; right?

22 A. Including the products.

23 Q. Okay. Now, the purpose of warning a patient
24 during the informed consent process is to allow that

1 patient to make a determination of whether she wants
2 to undergo the surgery; right?

3 A. It's -- patients are going -- are going to
4 eventually follow your -- the -- the doctor, the
5 doctor's advice. But the reason why you do the
6 informed consent is, more than the patient deciding,
7 which many times they -- they cannot decide, it's to
8 empower that patient with the information of this is
9 what I use for my decision, the decision that I
10 recommended to you.

11 Q. Okay. Ultimately, though, it is -- the
12 patient has the right to decide one way or another
13 what they want to do; right?

14 MR. SNELL: Form, overbroad.

15 A. Patient -- patients may -- may ask more
16 questions or may -- say "I will have a preference,"
17 but in 25 years seeing patients, patients will tell --
18 will ask you, "Doctor, tell me what you -- you think
19 is the best way of doing it and tell me why and how
20 you come to that decision."

21 Q. (By Mr. De La Cerda) Okay. So have you
22 ever had a patient say, after being consented or
23 receiving informed consent, saying, "No, I don't
24 want to have that procedure," as to mesh?

1 A. No, I -- I have not had that experience.

2 Q. Do you agree it's important for the
3 physician to have as much information about the risks
4 associated with transvaginal mesh or sling product so
5 that the physician can make an informed decision on
6 whether to recommend those products?

7 A. I think it's important that the physician
8 gets accurate and makes a reasonable effort to get
9 better on what they use and what they do every single
10 day.

11 Q. Including the information that they are
12 going to communicate to the patient; right?

13 A. It's especially if you're going to
14 communicate to the patient and -- especially when it
15 has to do with you making a clinical decision.

16 Q. Do you agree that physicians rely on a
17 transvaginal mesh manufacturer to provide them with
18 information about the risks and complications
19 associated with their transvaginal mesh products?

20 MR. SNELL: Objection, overbroad and
21 requires speculation.

22 A. I can't -- I cannot think for all the
23 physicians, but I -- I can tell you that their
24 responsibility is within ourselves before we use any

1 product.

2 Q. (By Mr. De La Cerda) Do you agree the
3 transvaginal mesh manufacturers are at least one
4 source of information that a physician can rely on
5 in obtaining information about their risks and
6 complications of transvaginal mesh products?

7 MR. SNELL: Objection, speculation.

8 A. It might be at the low end of the -- of the
9 evidence that we gather.

10 Q. (By Mr. De La Cerda) You're not saying
11 that a physician shouldn't rely on information from
12 a transvaginal mesh manufacturer about the risks and
13 complications of those products; right?

14 MR. SNELL: Form, overbroad.

15 A. I think that a physician needs to rely on
16 the best evidence, best clinical evidence, not just in
17 any sort of marketing communication or sales
18 communication. They need to know that the decision to
19 do surgery is a scientific process and they need to
20 read that.

21 Q. (By Mr. De La Cerda) If -- but certainly
22 if a transvaginal mesh manufacturer is providing a
23 serious warning about its products, even if that
24 warning hasn't played out in the scientific

1 literature, I mean, that's still something that
2 needs to be considered; right?

3 MR. SNELL: Form, overbroad.

4 A. There's a degree of information that you
5 need to consider. You -- you have -- you're a doctor
6 and you have the scientific information because that
7 allows you to analyze information better. So in that
8 regard, what we're going to see is information that is
9 relevant because they're at the highest level of
10 evidence, information that is less relevant because
11 they are the lowest one, but there's a -- there's a
12 hierarchy -- did I say that word okay? -- there is a
13 hierarchy of information and we're going to go for the
14 highest one.

15 Q. (By Mr. De La Cerda) Okay. Let's take a
16 silly example for a second. If the manufacturer of
17 transvaginal mesh knows that there's a
18 one-in-a-million chance that it explodes inside a
19 human body, but that is never played out in the
20 RCTs, never, ever been seen by anyone other than the
21 manufacturer, does that information need to be put
22 out to the public and told to physicians?

23 MR. SNELL: Objection. I'm going to have to
24 object, incomplete, purely speculative,

1 hypothetical.

2 Q. (By Mr. De La Cerda) The answer is of
3 course; right?

4 MR. SNELL: I don't know about that. I
5 mean, that's the doctor's answer, but my
6 objection is incomplete hypothetical, purely
7 speculative.

8 Go ahead.

9 A. The explosion thing is a little out there.
10 It's -- we have not seen any devices that actually
11 explode for prolapse or incontinence. I don't know
12 for the other ones.

13 The point I'm trying to come across is, to
14 answer your question, when we look at information, we
15 look at randomized control trials. Now, randomized
16 control trials in cohort studies, even case control
17 studies, you can go down to a list and you're going --
18 the methodology is what allows you to give
19 recommendations and form your counseling.

20 Q. (By Mr. De La Cerda) So even if the
21 manufacturer knows of severe life-altering
22 complications associated with its products, if that
23 severe life-altering complication hasn't played out
24 in the randomized control trials, you believe that

1 physicians shouldn't place much weight on that?

2 A. I think as humans -- as humans, if we see
3 that there is any -- any danger for anyone, for any
4 other human being, we'll just go and say it,
5 regardless of who we work for. And at the end it's
6 not a company, it's a group of people working. So the
7 human -- the human nature is to -- the human thing is
8 to actually do that, and that's our nature. But
9 that's different from having -- making a clinical
10 decision.

11 Q. Okay. So, ultimately, should information
12 like that, if it's known to manufacturer, but it
13 hasn't played out in the randomized control trials,
14 should information like that about severe
15 life-altering complications be communicated to a
16 patient during the informed consent process?

17 MR. SNELL: Form, asked and answered.

18 A. What we're going to use to counsel patients
19 is randomized control trials. And if -- if the
20 question is if the manufacturer should disclose it,
21 I -- I -- my opinion is probably most people would go
22 ahead and disclose it, but in terms of making a
23 clinical decision, we're going to use for the best
24 evidence that we have.

1 Q. (By Mr. De La Cerda) And I understand, I
2 definitely understand. I guess what I'm trying to
3 get at, though, is: Should that information be
4 communicated to the patient during the informed
5 consent process or not?

6 A. Only the information that is backed by good
7 science.

8 Q. Okay. So the answer is; no, right?

9 MR. SNELL: Objection, asked and answered.

10 A. If it's not -- if it's not backed by
11 science, it plays no role in the counseling of a
12 patient.

13 Q. (By Mr. De La Cerda) Including if the
14 manufacturer has discovered severe life-altering
15 complications that it knows of, even though it
16 hasn't been played out in the randomized control
17 trials and the medical literature; right?

18 A. Our counseling --

19 MR. SNELL: Same objection.

20 A. Our clinical counseling is evidence-based.

21 Q. (By Mr. De La Cerda) Okay. And evidence
22 from the manufacturer wouldn't necessarily count --
23 well, the finding of a manufacturer as to a severe
24 life-altering complication wouldn't count as

1 evidence under the framework that you're using;
2 right?

3 A. The -- the findings, whatever findings, that
4 being from a physician, that being from a patient,
5 that being from -- from a manufacturer or anybody
6 else, a group -- whatever findings needs to be
7 corroborated by evidence, that's why we have studies,
8 that's why we have a well-placed methodology for
9 evidence.

10 Q. And so the medical -- well, the studies are
11 going to be the foundation of that evidence, not some
12 information from the manufacturer; right?

13 A. Any -- any -- any radical information, that
14 being of things being too good or too bad need to be
15 evaluated on the light of a randomized control trial,
16 needs to be evaluated on if there is no randomized
17 control trial, needs to be evaluated based on the type
18 of the study that we have and the clinical experience.

19 Q. Do you consider a permanent injury a severe
20 side effect?

21 A. A permanent injury is different from a side
22 effect.

23 Q. Okay. So what -- so you don't believe that
24 a permanent injury is a severe side effect or they're

1 just totally different?

2 A. They're -- there's side effects and there's
3 injuries.

4 Q. Okay.

5 A. And the side effect has more to do with what
6 pertains to one particular product and an injury could
7 be from anything that is used in surgery.

8 Q. Do you consider a permanent injury a severe
9 injury?

10 MR. SNELL: Form, incomplete hypothetical.

11 A. I apologize for that.

12 Can you please repeat that?

13 (The requested portion of the record was
14 read back by the reporter.)

15 A. There could be permanent effects of surgery
16 that are not necessarily severe and severe that are
17 not exactly permanent.

18 Q. (By Mr. De La Cerda) Do you consider a
19 risk or complication that requires additional
20 surgeries a severe side effect?

21 A. Based on the -- on the -- on the evidence on
22 which -- which has a classification is not considered
23 severe, is not considered severe if he needs just to
24 go back to the operating room.

1 Q. So that's not severe in your eyes.

2 A. Yeah.

3 Q. Do you consider risk or complication that
4 seriously alters a patient's quality of life a severe
5 side effect?

6 A. It could be -- that side effect could be for
7 improvement of a quality of life, that could be --
8 that's an effect on the side or a side effect, the way
9 we usually recognize it, can be deteriorating to the
10 quality of life. I will have to look at the specific
11 situation and look at the specific data on it.

12 Q. Okay. Let's shift gears. The content and
13 substance of the professional education sponsored by
14 Ethicon on it's TVT, TVT-O, Gynemesh, Prolift and
15 Prosima did not and does not contradict the content
16 and substance of the IFUs for these products; correct?

17 MR. SNELL: Form, overbroad.

18 A. The content of the -- of these programs use
19 the IFU.

20 Q. (By Mr. De La Cerda) They don't
21 contradict it; right?

22 A. No, there is -- there is actually -- in the
23 presentations that you're going to see, they -- they
24 work -- they work together.

1 Q. Okay. Now, I figured the most efficient way
2 to do this, because now we'll get into the substance
3 of the various issues that you've opined on, there are
4 many of these issues that can be grouped together as
5 to all the products and I think that will be the
6 fastest way to get through it, so that's what I'm
7 going to do.

8 So, for example, I'm about to ask you about
9 the IFU. I'm going to ask you about -- these are
10 general questions about the IFUs of the TVT, TVT-O,
11 Gynemesh, Prolift and Prosima. I think we can do it
12 all at once.

13 A. Yes.

14 Q. First of all, are you familiar with the
15 contents of the various versions of the IFUs for the
16 TVT, TVT-O, Gynemesh, Prolift and Prosima?

17 A. I'm aware that they're -- they have changed
18 in 2015.

19 Q. And you're generally aware of the contents,
20 right, of those -- of those various IFUs?

21 A. Yes, there are IFUs that actually might be
22 able to tell you separate steps.

23 Q. Okay. Do you intend to offer an opinion as
24 to whether the warnings in the IFUs for the TVT,

1 TVT-O, Gynemesh, Prolift and Prosima were sufficient
2 to apprise doctors of the risks of those products?

3 A. Yes, I will -- I will give an opinion on
4 that.

5 Q. And your opinion will be that they were
6 sufficient warnings; right?

7 A. Yes, that will be my opinion.

8 Q. Do you know what standards Ethicon applied
9 in terms of what needed to be included in the warnings
10 in the IFUs for the TVT, TVT-O, Gynemesh, Prolift and
11 Prosima?

12 A. That's the standards apply?

13 Q. Yes.

14 A. I'm aware of certain standards that were
15 used for the IFU.

16 Q. Okay. And what were those?

17 A. The area on side effects, on warnings,
18 procedure steps, and the specifics on informing about
19 the need for specialized training to perform these
20 procedures.

21 Q. Do you know what -- do you know whether
22 there's any -- are there specific, like, written
23 standards, though, that you're aware of that Ethicon
24 used in deciding exactly what warnings would go in

1 there, what adverse reactions would go in there, and
2 what procedure steps would go in there? Do you know
3 if there's any written standards that Ethicon relied
4 on?

5 A. I'm -- I'm aware of that. As for many
6 products, they -- the ones that are disclosed are the
7 ones that are specific to that product.

8 Q. Okay.

9 A. In other words, they're not comprehensive
10 guides on incontinence or -- or prolapse care.

11 Q. Okay. Have you ever, in your career, been
12 involved in writing or preparing an IFU for a medical
13 device?

14 A. I have not written an IFU. I read -- I read
15 IFUs through most of my career.

16 Q. Have you ever studied the question of what
17 risks and complications were known to doctors across
18 the country with various background and levels of
19 experience with regard to the use of the TVT, TVT-O,
20 Gynemesh, Prolift and Prosima? Did you ever study
21 that question?

22 A. The risk with mesh were, with these
23 procedures in general, were addressed in a variety of
24 ways. And those were -- there were communications

1 from the American College of OB/GYN, there were
2 meetings that -- there were journals, there were so
3 many different -- different venues that we have grown
4 used to read and understand.

5 The IFU, we -- we all expected that it was
6 going to give us one specific set, but the other set
7 on the evidence, we expected that from our -- our
8 scientific data.

9 Q. So back to the question, though: Did you
10 ever study -- ever perform a study or ever study or do
11 questionnaires that determine what doctors actually
12 knew about these products, about the risks and
13 complications of those products? Did you ever perform
14 a study like that?

15 A. There was -- to my -- to my knowledge,
16 there's no -- not a study that have address -- address
17 it.

18 Q. And you, personally, haven't done a study
19 either; right?

20 A. No, I have not done -- done a study. I have
21 examined forms on evaluation of surgical skills that
22 at one time I use.

23 Q. Okay. But on this specific question, you
24 haven't actually performed a specific study looking at

1 what doctors actually knew about the risks and
2 complications associated with transvaginal mesh
3 products?

4 A. I have not performed such study.

5 Q. Do you agree that a surgeon should be able
6 to solely rely on the warnings and description of risk
7 and complications in the IFUs for the TVT, TVT-O,
8 Gynemesh, Prolift and Prosima?

9 MR. SNELL: Form, incomplete.

10 A. We -- we don't rely just on the IFU.

11 Q. (By Mr. De La Cerda) Do you agree that a
12 surgeon should be able to just rely on the IFU or do
13 you disagree?

14 MR. SNELL: Same objection, asked and
15 answered.

16 A. I -- I disagree that a surgeon should be --
17 rely just on the IFU.

18 Q. (By Mr. De La Cerda) Should the IFUs for
19 the TVT, TVT-O, Gynemesh, Prolift and Prosima
20 include the frequency, duration and severity of
21 risks associated with those devices?

22 MR. SNELL: Same objection, lacks
23 foundation.

24 A. No. As complete as an IFU could be, as

1 complete as an IFU may want to be, it would not be
2 able to address all of them. It may comply with what
3 we expect from the IFU, but it will not be able to
4 address every single -- every single risk that has to
5 do with a surgery that is much more complicated than
6 what an IFU can address.

7 Q. (By Mr. De La Cerda) The IFUs for the TVT
8 TVT-O, Gynemesh, Prolift and Prosima should include
9 all known material risks associated with these
10 products; right?

11 MR. SNELL: Form, asked and answered.

12 A. It should -- it should include all -- all
13 unknown risks about the material, but not necessarily
14 will address all known material risk.

15 Q. (By Mr. De La Cerda) The IFUs for the
16 TVT, TVT-O, Gynemesh, Prolift and Prosima should
17 include all characteristics of these products that
18 can significantly increase the risk of severe
19 complications; right?

20 MR. SNELL: Object to form, lacks
21 foundation. This was asked and answered earlier.

22 A. Is the -- the instructions for use for the
23 device, it addresses one area. The -- the rest is
24 based on the data.

1 Q. (By Mr. De La Cerda) So is that a no?

2 A. No, that's not necessarily a no. Actually,
3 that's -- that's exactly -- the IFU cannot -- cannot
4 be a comprehensive guide.

5 Q. So what -- what characteristics of these
6 products -- strike that.

7 Do you believe that the IFUs for the TVT,
8 TVT-O, Gynemesh, Prolift and Prosima sufficiently
9 address any characteristics of those products that
10 could significantly increase their risk of severe
11 complication?

12 MR. SNELL: Objection.

13 A. As it pertains to the product, yes.

14 Q. (By Mr. De La Cerda) The information in
15 the IFUs for the TVT, TVT-O, Gynemesh, Prolift and
16 Prosima should be truthful; correct?

17 A. Yes.

18 Q. The information in the IFUs for the TVT,
19 TVT-O, Gynemesh, Prolift and Prosima should be
20 accurate; correct?

21 A. Yes.

22 Q. The information in the IFUs for the TVT,
23 TVT-O, Gynemesh, Prolift and Prosima should be
24 complete; correct?

1 MR. SNELL: Objection, form. Prior
2 testimony.

3 A. It is complete -- it is complete for the
4 product. That's my -- my opinion.

5 Q. (By Mr. De La Cerda) The information in
6 the IFUs for the TVT, TVT-O, Gynemesh, Prolift and
7 Prosima should be fair and balanced about the risks
8 and benefits of these products?

9 MR. SNELL: Same objection.

10 A. It -- it should be fair and balanced for
11 what pertains to the product.

12 Q. (By Mr. De La Cerda) Once an IFU is out
13 there and -- for physicians to review, if Ethicon
14 learned of a risk or complication that was not
15 previously warned about in the IFU and it was a
16 significant risk or complication in terms of the
17 harm it caused to women, do you know whether or not
18 Ethicon had an obligation to get that information in
19 the IFU?

20 MR. SNELL: Objection, hypothetical, legal
21 standard.

22 A. As long as it's evidence-based, yes.

23 Q. (By Mr. De La Cerda) Have you compared
24 the differences between the IFUs for the TVT, TVT-O,

1 Gynemesh, Prolift and Prosima, are you aware of the
2 differences between them?

3 A. I have -- I have read those -- read those --
4 and I have read them many times and I have use it to
5 explain the procedure.

6 Q. And so you've seen that over time there's
7 been some updates to the IFUs; right?

8 A. Yes, I have seen that.

9 Q. Is there a single long-term randomized
10 control trial for TVT, TVT-O, Gynemesh, Prolift or
11 Prosima with safety as a primary end point?

12 A. I -- I -- they don't -- they're not all
13 included. There is a randomized control trial that
14 explains about safety of Gynemesh, there is a
15 randomized control trial that explains for Prolift.

16 For each one of them, there's -- safety have
17 been included. Not only have those randomized control
18 trials explain about safety, they have -- it has
19 spoken specifically about the percentage and the
20 clinical significance of each one of the
21 complications.

22 Q. Are any of the studies that you're
23 referencing there, has the primary end point, though,
24 been safety in the study?

1 A. The safety -- the safety was evaluated on --
2 on Gynemesh.

3 Q. Do you know what the name of that study was?

4 A. Yes, yes.

5 Q. There is another one over here too.

6 A. Gynemesh. Gynemesh on the -- okay. So --
7 so on the -- to begin with the mesh, we have the
8 Flood, F-l-o-o-d, paper on the use of Marlex.

9 Q. And what does that study show?

10 A. That's for the anterior colporrhaphy
11 reinforced with Marlex mesh for treatment of
12 cystocele.

13 Q. Is this one of the studies that shows it has
14 a primary end point of safety?

15 A. It's not titled "safety," but they -- they
16 conclude on that study that this is safe to use. And
17 then there's Nicita, Giulia.

18 Q. How do you spell that?

19 A. Giulia Nicita, N-i-c-i-t-a.

20 Q. And what is that study?

21 A. And it shows exactly applications in terms
22 of they were able to save -- to do it with safety.

23 So to be accurate to the response to your
24 question, there's no study that says safety of

1 Gynemesh on -- or safety of Marlex in the use -- use
2 on -- for cystocele repair.

3 There's -- there are multiple studies -- I
4 can go on with the list -- that cites safety as one of
5 the -- of the things that they study.

6 Q. So the point of this -- by the way, this is
7 not my question. I never -- this question, to me,
8 never really gets me anywhere.

9 But the point is that all the studies that
10 have been done on any of these mesh products, the
11 number one end point is, is it effective; right? Is
12 it effective and then, by the way, was it safe, too?

13 None of these studies is like number one
14 thing safety; right?

15 MR. SNELL: Objection, overbroad.

16 A. The -- there's even a better level of
17 evidence that speaks about safety and is when you
18 compare the use of any of these products with what
19 has -- with the -- with the safety profile when you
20 don't use the product. And that's where the
21 randomized control trial comes into -- into play.

22 The randomized control trials has the
23 capability of evaluating something that I have use
24 without mesh and compare it with something with mesh.

1 And that has been used -- that has been reported for
2 Gynemesh, it has been reported for Prolift, it has
3 been -- was reported for -- for TVT and TVT-O, and it
4 was so -- so consistently demonstrated that when it
5 came to Prosima, it became a cohort study.

6 Q. (By Mr. De La Cerda) Is it -- is it your
7 opinion that the studies show that any time that
8 mesh products have been compared to whatever the
9 alternative was, a non-mesh alternative, that the
10 mesh products have been shown to be safer than the
11 non-mesh alternative?

12 A. It's -- it has been shown not to have
13 statistically significantly increased in the number of
14 complications or the frequency of these complications.

15 Q. Right. But that's a good point. So it's
16 been shown to be as safe; right? And really, the
17 differentiating factor is whether it's more effective;
18 is that fair?

19 A. It has been shown to be as safe and in some
20 situations, it has been shown -- it has shown to be
21 even safer.

22 Take, for example, the use in the initial
23 study of Marcus Carey on mesh, on Prosima, and
24 straight -- and the known use of an implant.

1 When you compare, you see that the three
2 patients that he had to operate for vaginal stenosis
3 were the ones that did not have a mesh. So there you
4 have an instance in which there was more complications
5 with -- by not using mesh than by using the mesh.

6 Is that directly related to the mesh? And
7 that's something that could be addressed with a
8 randomized control trial.

9 When we do sutures, suture repairs, and we
10 call them "native tissue repairs," in a randomized
11 control trial or even when we do a cohort of sutures,
12 we see complications on sutures in 36% of uterosacral
13 ligament suspension, we see suture complications in
14 sacrospinous ligament fixations, and when they're
15 compared with mesh, there is -- there is much less.

16 Q. So on the issue of whether -- you know, the
17 FDA came out with an opinion about -- they actually
18 described that repairs with pelvic organ prolapse mesh
19 are no more effective and might be more dangerous than
20 the alternative non-mesh repairs; right?

21 MR. SNELL: Objection to foundation.

22 A. That -- that was the -- that was an opinion
23 that they came in, in the small panel, analyzing the
24 data, I don't know, for two, three days, but that's

1 not -- I don't know for how many days they analyze it.
2 I don't even know what papers they consider.

3 But the preponderance of the evidence in the
4 randomized control trial is that it's not more
5 dangerous.

6 Q. (By Mr. De La Cerda) Okay. So on that
7 particular -- I'm sorry.

8 A. I apologize. I'll just turn it off.

9 Q. So on that particular issue, you disagree
10 with the FDA; right?

11 MR. SNELL: Form, foundation.

12 I think that's misleading because there's
13 two different time periods, Counsel.

14 A. I -- I disagree -- I disagree with -- with
15 the FDA opinion based on everything else that I review
16 and that I present on my report.

17 Q. (By Mr. De La Cerda) All right. Let's
18 shift gears a little bit and talk some about this is
19 a TVT and TVT-O issue.

20 You're aware that the TVT and the TVT-O can
21 either be mechanically cut into its sling shape or
22 laser cut into its sling shape; right?

23 A. It can -- the edges can be mechanically cut
24 or laser cut or personally cut.

1 Q. You're aware that Ethicon had evidence as
2 early as 2006 that after elongation, mechanically cut
3 mesh has a greater tendency than laser cut mesh to
4 degrade, lose particles, lose structure, rope, fray
5 and curl; right?

6 MR. SNELL: Form. Form, foundation.

7 Go ahead.

8 A. What -- what I saw in a picture was an
9 uniaxial test done in a sling beyond the capabilities
10 of a sling and beyond any forces that could be placed
11 on a sling when used properly.

12 Q. (By Mr. De La Cerda) But you also saw in
13 those pictures that at least under those
14 circumstances, the mechanically cut mesh as compared
15 to the laser cut mesh had a tendency to lose
16 particles, lose structure, rope, fray and curl;
17 correct?

18 A. They -- they show particles that we -- we
19 have seen over -- over time, not only on that, but
20 also in sutures. They -- in a picture, I saw a
21 picture of it, and I saw the pictures of uniaxial
22 testing and I saw the communications about it, but
23 that's as much as I can say, I saw it.

24 Q. And you know that that information was in

1 the files of Ethicon at least as of 2006; right?

2 A. I -- I don't know the time when the
3 information was.

4 Q. Have you personally seen a TVT or TVT-O that
5 has lost particles, lost structure, roped, frayed or
6 curled in your practice?

7 A. The only time that I have seen it stretch
8 like that is when I'm actually -- one that I was
9 removing that I put a lot of force into it. That's --
10 that's a way much force that any patient could ever
11 generate with a sneeze or cough.

12 Q. You mentioned the one patient that you had
13 that you're removing the sling where it's too tight?

14 A. Right.

15 Q. Is this the person you were talking about?

16 A. That might be the same person; I cannot tell
17 you with certainty.

18 Q. So when the mesh was placed too tightly, you
19 saw -- would you call that roping or what was it that
20 you actually saw?

21 A. I -- I -- I started dissecting it and I saw
22 that she still had some -- and the only way I can -- I
23 can recall it is because I actually saw those pictures
24 yesterday in one of the -- of the slide sets.

1 And all I could -- all I could see was that
2 I actually had to -- had to pull on it from inside,
3 normal attachment. This was not roped, this was not
4 curled, this not -- there's no such thing that I could
5 describe in telling in general terms or in scientific
6 terms. I -- this was one -- one anecdotal case in
7 which I -- that's the only one that looks like the
8 dimensions stretch -- stretch on that device.

9 Q. So would your testimony be that you've never
10 seen a TVT or TVT-O mechanically cut, lose particles,
11 lose structure, rope, fray or curl in your own
12 practice?

13 A. No, because it has a plastic sheath.

14 Q. So you've never seen that yourself?

15 A. No.

16 Q. Should the mechanically cuts -- strike that.
17 Excuse me.

18 Should mechanically cut meshes tendency
19 to -- in comparison to laser cut mesh -- so should
20 that tendency to degrade, lose particles, lose
21 structure, rope, fray or curl be included in the IFU
22 for the TVT and TVT-O or no?

23 MR. SNELL: Objection, foundation.

24 A. I don't find a need to include that because

1 that's something that has not been demonstrated
2 consistently.

3 Q. (By Mr. De La Cerda) Is that -- is that
4 your basis for that opinion or are there
5 additional -- is there additional information that
6 provides a basis for that opinion?

7 A. I have not seen any scientific evidence that
8 the mesh curls or ropes or -- or -- or frays. Nothing
9 that I can -- I can tell you that, okay, this is --
10 we -- we saw this observation on this patient and we
11 have reported it consistently or out of this number of
12 procedures that we did, this number actually showed
13 that. And if it happened, what is -- how does that
14 translate into the clinical -- and I keep talking with
15 my hands because -- that will never get into the
16 deposition, but the -- on the -- I have not seen that
17 be reported or how that can translate into clinical --
18 into clinical behavior.

19 Q. So on this issue, the basis for your opinion
20 is really the absence of information supporting this
21 information should be in the IFU; right?

22 A. And the fact that there are multiple
23 randomized control trials well -- well-designed
24 control trials, surgical trials by good surgeons

1 within groups that are well-respected within my
2 specialty, that have not describe, not in a single
3 time, not in any of these papers, that there is such a
4 thing happening.

5 Q. If mechanically cut mesh's tendency in
6 comparison to laser cut mesh to degrade, lose
7 particles, lose structure, rope, fray and curl is
8 clinically significant or clinically relevant, should
9 it be included in the IFU for the TVT and TVT-O?

10 A. It --

11 MR. SNELL: Objection. Hold on, give me a
12 minute.

13 Objection, improper hypothetical based on
14 the particle.

15 A. It would have -- it would have to be
16 reported. It would have to be reported by
17 something -- by something dependent by randomized
18 control trial.

19 If -- any attributes that being on any of
20 the polar sides of things -- things working at one
21 level or another in both sides of the spectrum needs
22 to be validated by scientific testing.

23 Q. (By Mr. De La Cerda) This is a question
24 that I'll have throughout several of these opinions.

1 I want to make sure to say it in a way that you
2 would agree with, because I want you to define for
3 me what it would require for this information to
4 suddenly be required to be in the IFU.

5 And so what -- what would be required from
6 your perspective for the information about the
7 differences between a mechanically cut and laser cut
8 mesh on the issue of degradation, loss of particles,
9 loss of structure, roping, fraying, curling, what
10 would it take for that information to suddenly be
11 information that needs to be in the IFU?

12 MR. SNELL: Objection, same objection as
13 before.

14 A. To make it to the -- to the IFU, needs to be
15 something that is independent of -- of just -- just
16 the technique beyond what's described in the IFU. If
17 you see something like a device or a suture breaking,
18 it needs -- the IFU should say, do not make it so
19 tight or place a spacer under the urethra in the case
20 of slings. The IFU says that.

21 So -- so -- and the insertion of the needle
22 or the removal of the plastic sheath is being done,
23 there needs to be instructions in the IFU for the
24 appropriate placement. So this -- this is not about

1 saying this mesh curls or ropes or -- that's not --
2 that's not what the -- what I expect from IFU. What I
3 expect is give me the proper technique so I don't put
4 this material to this extremes that would cause it to
5 behave this way.

6 Q. (By Mr. De La Cerda) So I understand
7 the -- first it would need to be independent of the
8 technique, but if the roping, fraying, curling, loss
9 of structure, if it's clinically relevant and
10 statistically significant, that would need to be in
11 the IFU; right?

12 MR. SNELL: Objection, improper
13 hypothetical, vague.

14 A. And to the -- and to the level that it would
15 say, okay, this is -- this is how it happens in the
16 clinical setting, not just in a machine.

17 Q. (By Mr. De La Cerda) And I guess that
18 would be encompassed though -- I mean, if it's
19 statistically significant through randomized control
20 trials -- let me think about that. So it would need
21 to be shown through randomized control trials that
22 actually involve human implants, not just benched-up
23 testing or whatever it is in the lab; right?

24 A. If you blind -- if you blind this study in a

1 way that physicians don't know which type of mesh
2 they're -- they're using, you could -- that would be a
3 good start.

4 Q. Okay. Do you know if Ethicon ever performed
5 a test like that, where they compared laser cut mesh
6 versus mechanically cut mesh actually implanted in
7 women?

8 A. I -- I don't see anyone placing any human
9 through the stress that a machine could do -- could do
10 that.

11 Q. But Ethicon never performed a study like
12 that; right?

13 A. I'm going to give you a better -- that was a
14 very unclear answer what I just gave you.

15 I don't see -- I don't see an implant being
16 stressed to the forces that could be done in uniaxial
17 testing. Uniaxial testing doesn't always translate
18 into the behavior in the human body.

19 The IFU was good in addressing the area that
20 was most important on the urethra and the design was
21 good in addressing the placement and the -- and the
22 confirmation of the mesh with the minimum of the
23 formation.

24 Q. But back to the question. Ethicon never

1 performed a study comparing mechanically cut mesh
2 versus laser cut mesh in -- actually in women; right?

3 A. It's --

4 MR. SNELL: Foundation.

5 Go ahead.

6 A. It's -- I'm not aware of any study that was
7 performed like that, in that model.

8 Q. (By Mr. De La Cerda) If mechanically cut
9 mesh, TVT or TVT-O, loses particles when its
10 implanted in a woman, is there potential for those
11 lost particles to migrate into the woman's vaginal
12 wall and cause pain?

13 A. That's a hypothesis. It has never been
14 demonstrated.

15 Q. Do you know if it's possible or no?

16 A. It's medically -- it's medically --
17 medically possible, which is way below that within
18 the -- within the settings of certain medical
19 probability.

20 Q. Okay. Still on this mechanically cut versus
21 laser cut issue. You agree that mesh -- that mesh and
22 polypropylene slings that is too stiff or rigid can
23 increase the risk of complications like erosion,
24 voiding dysfunction, and urethral obstruction; right?

1 MR. SNELL: Form.

2 A. No -- no study has been able to corroborate
3 that.

4 Q. (By Mr. De La Cerda) So would you
5 disagree with that statement?

6 A. I -- I would disagree to that statement
7 based on the fact that there's no evidence confirming
8 it.

9 Q. You know that in 2004, Ethicon tested laser
10 cut mesh and found it to be more rigid or stiffer than
11 mechanically cut mesh; right?

12 A. Regardless of the findings that Ethicon may
13 have found, I'm not aware that they found one way or
14 the other, and with all the research, it would not
15 surprise me that they may have found one way or the
16 other. The question is if that has any -- any
17 translation to clinical symptoms and the ans- -- of
18 the ones you described, and my answer to that is no
19 evidence of it.

20 Q. Okay. So that leads to the next question
21 and this is a question I'm going to have with all
22 these opinions, but should laser cut mesh's greater
23 stiffness or rigidity in comparison to mechanically
24 cut mesh be included in the IFUs for the TVT and

1 TVT-O?

2 MR. SNELL: Objection, lacks foundation.

3 A. No -- no -- there's no evidence that it
4 could work one way or the other. Why would they
5 include it in the IFU?

6 Q. (By Mr. De La Cerda) Okay. So let's talk
7 about the bases for why it doesn't need to be
8 included in the IFU. What is your basis for that?

9 A. It's a -- the use of a laser cut or
10 mechanical cut meshes do not translate into your
11 procedure being performed any differently and they --
12 with laser cut or without or with mechanical cut, what
13 you need to be aware is not to place a sling under
14 excessive tension, which is something that we have
15 learned even before there was mesh, not to place a
16 sling under excessive tension, follow good surgical
17 principles. And if there was any question about that,
18 then doctors could have -- could have requested to be
19 trained on it, but I would not include something on
20 the IFU that would just confuse the issue on how to --
21 how to perform the procedure.

22 Q. Okay. If laser cut mesh has greater
23 stiffness or rigidity in comparison to mechanically
24 cut mesh, is clinically relative and statistically

1 significant, should it be included in the IFUs for the
2 TVT and TVT-O?

3 MR. SNELL: Objection, lacks foundation,
4 improper hypothetical.

5 A. There's -- there's no correlate it
6 clinically. So my answer to that is no, I would not
7 expect them to write in the IFU.

8 Q. (By Mr. De La Cerda) So this is a
9 hypothetical. I'm saying assume that it's
10 discovered to be clinically relevant and
11 statistically significant, under those circumstances
12 would it then be proper to put it in the IFU?

13 MR. SNELL: Same objection.

14 A. If it's clinically -- clinically relevant or
15 statistically significant, then it may have been
16 included on the IFU if it pertains to the performance
17 of the procedure.

18 Q. (By Mr. De La Cerda) Now, you're aware
19 that -- you know Ulmsten is the original -- one of
20 the original inventors of the TVT; right?

21 A. Yes.

22 Q. You know a couple of the guys that studied
23 TVT with him were Nilsson and Falconer, you remember
24 those names being mentioned in the studies?

1 A. Yes.

2 Q. And you're aware that Nilsson and Falconer
3 opposed the use of laser cut mesh because it did not
4 have the same stretch profile of mechanically cut
5 mesh. Are you aware of that?

6 MR. SNELL: Form.

7 Go ahead.

8 A. I am not aware of their internal
9 conversations about it.

10 Q. (By Mr. De La Cerda) And does that have
11 any effect on your opinion one way or the other?

12 A. It doesn't. Whatever -- whatever
13 interaction they had, I would consider just a healthy
14 scientific exercise, but until there's data supporting
15 its use and there's data showing that there is a
16 difference in performance, there is no need to make a
17 difference -- to make a different recommendation.

18 Q. What is the proper way to tension the TVT
19 device?

20 A. It's -- it's to do it tension-free and
21 tension-free means that there is preservation of the
22 width of the sling up to 75 percent.

23 Q. I think I missed something. What did you
24 mean -- can you explain that again?

1 A. By the time that I finish doing my
2 procedure, the width on my TVT needs to be at least
3 1.1 -- at least 75 percent of 1.1-centimeter, that's
4 not just with TVT --

5 Q. Okay.

6 A. -- that's with any sling that I may place.

7 Q. Where is that information in the IFU?

8 A. That's not going to be in the IFU because
9 that's an observation of Jaime Sepulveda.

10 Q. Do you believe that Ethicon is responsible
11 to tell physicians how to properly tension the TVT?

12 A. There's -- there's -- there's information on
13 the IFU about not overtensioning.

14 Q. There's information about that, but is there
15 information, like an exact measurement on how to
16 tension? For example, I liked your example of
17 75 percent of 1.1 centimeters.

18 Does Ethicon have a responsibility to
19 communicate to physicians an exact way in tensioning
20 the TVT?

21 MR. SNELL: Form.

22 A. I think that Ethicon make every possible
23 effort through their -- through their education
24 programs to -- to emphasize good practices in doing a

1 sling. Ethicon is not re-inventing our technique to
2 do a continence procedure.

3 Q. (By Mr. De La Cerda) When you taught on
4 behalf of Ethicon regarding slings, did you discuss
5 this issue of the 75 percent of 1.1 centimeters
6 indicating proper tensioning?

7 A. That's a concept that we all have -- have --
8 we, as surgeons, we know we don't want to bring it
9 tighter than that. But we learned that with the
10 pubourethral slings.

11 Q. Okay. So are you saying no, you didn't
12 personally discuss that issue or because everyone
13 already knew it anyway?

14 A. Right. This is -- this is a common surgical
15 knowledge, which Ethicon may or may not have known. I
16 don't know if they -- if they knew it. This is just a
17 personal observation.

18 Q. So you believe that Ethicon properly
19 instructs physicians on how to tension the TVT; right?

20 A. They -- they cover that in the IFU.

21 Q. Do you agree that the strongest unmet need
22 with the TVT is the ability to adjust tension both
23 intraoperatively and post-operatively?

24 MR. SNELL: Form.

1 A. Well, there's no -- no way to assess
2 post-operatively. You're going to close and there's
3 no -- no study that says how you're going to tension
4 it. We try to make an inference with biomechanics.

5 Q. (By Mr. De La Cerda) But do you agree
6 with that statement? That the strongest unmet need
7 of the TVT's ability to adjust tension both
8 intraoperatively or post-operatively, do you agree
9 or disagree with that statement?

10 A. I --

11 MR. SNELL: Form.

12 Go ahead.

13 A. I would agree to an extent, but it's so --
14 so vague that I cannot tell you that I agree
15 completely with it.

16 Q. (By Mr. De La Cerda) Do you agree that
17 the mesh and TVT may be too wide?

18 MR. SNELL: Form.

19 A. I don't -- no, I think it has shown to be of
20 the -- of the right -- of the right width to work
21 clinically.

22 Q. (By Mr. De La Cerda) Do you agree that
23 there is no calibration to let you know when you
24 have the tension right?

1 A. That's -- that's part of the art of surgery
2 that I described before.

3 Q. So you do agree with that; right?

4 A. Repeat that.

5 Q. So do you agree with, quote, there is no
6 calibration to let you know when you have the tension
7 right, close quote?

8 A. No, we know -- we know when the tension is
9 right. We have experience -- enough experience to
10 know when the tension is right.

11 It's extremely subjective, but I can tell
12 you if you, at the end of your surgery, you see that
13 width that goes underneath, that width that has been
14 shown study after study, that is effective, if you
15 know that is not the width you have at the end of your
16 surgery, you overtensioned it.

17 Q. But there's not like a general calibration
18 for that; right? Or is there? I mean, is the general
19 calibration the 75 percent of 1.1 centimeters, is that
20 the general calibration for everybody or no?

21 MR. SNELL: Form.

22 A. It's a visual inspection.

23 Q. (By Mr. De La Cerda) So is that a yes?

24 MR. SNELL: Objection, asked and answered.

1 A. Yeah, that's a general calibration that is
2 been used -- I'm sorry, Burt.

3 MR. SNELL: I said, objection, asked and
4 answered.

5 Go ahead and answer it.

6 Q. (By Mr. De La Cerda) Do you agree that
7 there is no -- quote, there is no consensus on the
8 amount of tension needed and many feel that the
9 tension will vary based on patient presentation and
10 patient anatomy? Do you agree with that?

11 MR. SNELL: Form.

12 A. It's -- I would have to agree that it
13 changes from patient to patient and that's one of the
14 biggest challenges not only in this proceeding, any
15 surgery.

16 Q. (By Mr. De La Cerda) Are you going to
17 offer the opinion that tensioning of the TVT sling
18 is the same regardless of whether the sling is made
19 of mechanically cut mesh or laser cut mesh?

20 A. You're going to visually see at the end of
21 your procedure and you know if you tensioned it right
22 when you look at it.

23 Q. So tensioning might change as long as the
24 width that you're looking for is correct?

1 A. I just say visually see. I don't know how
2 another way you're going to see if it's not visually.

3 Q. Right.

4 A. But it's -- what I -- my opinion is that
5 once you -- once you place a sling, that being laser
6 cut or mechanically cut, at the end of your procedure,
7 that sling needs to look the way -- in a way that it
8 covers the mid urethra to an extent of at least .75 to
9 1-centimeter.

10 Q. Do you agree that a responsible medical
11 device company would determine the proper way to place
12 a device before putting that product on the market?

13 MR. SNELL: Form.

14 A. They -- they have no way -- we have no way
15 to -- to -- to communicate that to each other. That
16 is -- that is the hard part of surgery.

17 I think that when they say, "Do not
18 overtension it," and when they say, "You need to have
19 experience in continence procedures," and when they
20 say, "This is not a comprehensive guide for continence
21 care," I think that's accurate and fair and as a
22 surgeon you understand that.

23 Q. (By Mr. De La Cerda) And so this question
24 is really more of a general proposition, though.

1 Would you agree that a responsible medical device
2 company would determine the proper way to place a
3 device before putting that product on the market?

4 MR. SNELL: Same objection, asked and
5 answered.

6 A. That's where -- that's where all the studies
7 with cadavers come in.

8 Q. (By Mr. De La Cerda) So the answer is
9 yes; right?

10 A. Yes, the device company does that.

11 Q. Okay. Shifting gears to a new issue.

12 Before I do that, are you okay? Do you want
13 to take a break at all?

14 A. No, I'm okay, if you guys are okay.

15 MR. SNELL: What time are we going to have
16 lunch?

17 MR. DE LA CERDA: Yeah, it's almost noon.
18 Do you want to do it now.

19 MR. SNELL: If he's fine, I'm fine.

20 (Thereupon, a recess was taken from
21 11:47 a.m. until 12:00 p.m., after which the
22 following proceedings were held:)

23 Q. (By Mr. De La Cerda) So we're back on the
24 record.

1 There's a fault question on -- earlier we
2 discussed your work as a consultant for Ethicon and we
3 briefly discussed what you estimated to be what you
4 had received from Ethicon in compensation for that.

5 In another case, the Raviola case, which you
6 may recall, there was actually a production of the
7 payments and it was produced in a -- in hard copy --
8 and this question is probably really for Burt.

9 MR. DE LA CERDA: If I forward that to you,
10 can you send that to us in like an Excel or
11 whatever it originally came in because the print
12 is tiny?

13 MR. SNELL: Okay. Yeah, I mean -- well, I
14 can do my best.

15 MR. DE LA CERDA: Okay.

16 MR. SNELL: I've been trying to send
17 e-mails. My e-mail is not working. It's not
18 letting me send stuff. I have something
19 important to send. It's not related to this
20 deposition. I've been trying all morning. Is
21 the Internet --

22 MR. DE LA CERDA: It's coming off and on for
23 me.

24 I'm forwarding this to you and then if we

1 can get the native version. It looks like it was
2 an Excel that was then printed off, but the type
3 on it is really small and then that will
4 provide -- this is what Ethicon shows its records
5 of payments and then that can kind of settle that
6 issue.

7 THE WITNESS: Yeah, it was actually
8 presented on the Cavness trial.

9 MR. DE LA CERDA: Oh, okay.

10 THE WITNESS: It was in very small -- very
11 small letters.

12 MR. DE LA CERDA: Okay.

13 THE WITNESS: And just as clarifying that
14 number, what was allocated to pay me, not actual
15 payments.

16 MR. DE LA CERDA: Okay. So we'll have to
17 clear that up, but if, Burt, you can take a look
18 at getting us that version, thanks.

19 Q. (By Mr. De La Cerda) Okay. All right.

20 The issues that I'm about to discuss will relate to
21 TVT, TVT-O, Gynemesh, Prolift and Prosima, so I'm
22 going to do it all at once.

23 First, you're aware that the TVT and TVT-O
24 are made of Prolene mesh, which is constructed of

1 knitted filaments of extruded polypropylene strands,
2 identical in composition to that used in Prolene
3 polypropylene nonabsorbable surgical suture; correct?

4 A. I agree with that.

5 Q. You're also aware that the mesh in Gynemesh,
6 Prolift, and Prosima is Prolene Soft, which is also
7 constructed of knitted filaments of extruded
8 polypropylene identical in composition to Prolene
9 polypropylene suture; correct?

10 A. To a -- to a -- identical in composition,
11 yes.

12 Q. And the IFUs for the TVT, the TVT-O,
13 Gynemesh, Prolift and Prosima all characterize Prolene
14 as inert; correct?

15 A. They -- they characterize it as that word
16 inert, yeah.

17 Q. They state: "This material, when used as a
18 suture, has reported to be nonreactive and retain its
19 strength indefinitely in clinical use"; right?

20 A. I -- I'm aware of that statement, yes.

21 Q. They also -- the IFUs for those products
22 also state: "The material is not absorbed nor is it
23 subject to degradation or weakening by the action of
24 tissues enzymes"; right?

1 A. That's a statement on the IFU.

2 Q. The mesh in these products not being -- or
3 strike that.

4 The mesh in these products being nonreactive
5 or inert or not subject to degradation, that's a
6 property or those are properties that are desirable
7 for an implant designed for a human body; right?

8 MR. SNELL: Form, overbroad.

9 A. That -- that is -- that is a characteristic
10 that we did not see in other types of materials and
11 that we're pursuing when we placed those sutures.

12 Q. (By Mr. De La Cerda) Okay. Why would you
13 want a human -- an implant designed to be implanted
14 in humans to be inert or nonreactive or not subject
15 to degradation?

16 MR. SNELL: Objection, overbroad.

17 Go ahead.

18 A. The degradation has to -- has to do with --
19 the way we interpret degradation has to do with
20 absorbables or partially absorbable sutures.

21 The way that non- -- nonreactive means that
22 there's no reaction to hydrolysis.

23 And the way that it was described as non- --
24 nondegraded is it was that there was no loss on the

1 strength of the suture on testing that was done before
2 placing it on a patient.

3 Q. (By Mr. De La Cerda) Okay. So why would
4 it be desirable for a human implant to have those
5 characteristics that it doesn't degrade, that it's
6 inert, that's it's nonreactive?

7 MR. SNELL: Same objection.

8 Go ahead.

9 A. It is -- it translates, theoretically, on
10 the durability of the repair.

11 Q. (By Mr. De La Cerda) Because these mesh
12 implants are intended to be permanent implants;
13 correct?

14 A. They're intended to -- to last a lifetime if
15 you can make it interact in a way that it can last a
16 lifetime. In other words, if the host doesn't change,
17 you'll want that implant to work and give you
18 durability.

19 Q. Now you're aware that as early at 1987,
20 Ethicon had evidence of degradation of Prolene in the
21 human body; correct?

22 A. I -- I don't believe that they call it
23 degradation in the sense that we interpret
24 degradation. There's -- there's degradation from the

1 biomechanical point of view and there's degradation
2 from what we see in normal life of degradation.

3 Q. Okay. So what is it that you believe that
4 Ethicon saw in terms of degradation in 1987?

5 A. Well, what they saw -- what they saw is
6 purely a microscopic study. If there will be
7 degradation, there will be a significant impact on the
8 durability of the effect of the sling or in the
9 durability of the repair.

10 Q. In the context of safety, though -- strike
11 that.

12 If Prolene has a tendency to degrade in a
13 human body, would that indicate that it's not inert?

14 MR. SNELL: Form, improper hypothetical.

15 A. If it would degrade, it would dissolve. And
16 if it would dissolve, it would just lose all its
17 effect. So whatever -- whatever conclusion is met of
18 degradation is on hypothetical grounds and not based
19 on the evidence that we have.

20 Q. (By Mr. De La Cerda) What evidence are
21 you referencing?

22 A. The durability of a procedure for
23 incontinence on prolapse.

24 (Brief interruption and off the record discussion.)

1 Q. I can't remember if you were finished with
2 your response. If you could read it back.

3 (The requested portion of the record was
4 read back by the reporter.)

5 A. Let me clarify this. The reason why I
6 generalize it on incontinence on prolapse is because
7 we're talking about more than one product here.

8 Q. (By Mr. De La Cerda) Yes, yes.

9 And all these products have, within their
10 mesh -- one mesh is called regular Prolene or just
11 Prolene and the other one is called Prolene Soft, but
12 both meshes are made of essentially woven Prolene
13 suture. It's the same material as Prolene; right?

14 MR. SNELL: Objection.

15 A. No, it's not woven.

16 Q. (By Mr. De La Cerda) How is it made then?

17 A. It's knitted.

18 Q. Knitted, okay.

19 But it's all made of knitted polypropylene
20 that's identical in composition to Prolene; correct?

21 A. It's knitted -- it's knitted extruded
22 polypropylene.

23 Q. It's identical in composition to Prolene
24 suture; right?

1 A. It is -- it has been shown to have the same
2 level of crystallinity as Prolene suture.

3 Q. If there were findings as to Prolene suture,
4 would those findings, the characteristics of Prolene
5 suture, have relevance to meshes that are also made of
6 extruded polypropylene that's identical in composition
7 to Prolene suture?

8 MR. SNELL: Form, vague.

9 A. I did not get that one. Sorry.

10 (The requested portion of the record was
11 read back by the reporter.)

12 A. As it pertains to composition, the evidence
13 shows that TVT-O and Prolene sutures, that's the
14 extent of the evidence, has -- has the same
15 crystallinity. When we define crystallinity, is the
16 most accurate way to evaluate that one material is
17 like the other.

18 Q. (By Mr. De La Cerda) Well, what I'm
19 saying, though, is if there is a finding about a
20 characteristic of Prolene sutures like, for example,
21 degradation, if Prolene sutures degrade in the human
22 body, can we also say or is that evidence of that
23 Prolene mesh would also degrade in the human body?

24 MR. SNELL: Form.

1 A. And there is -- first of all, there is
2 more -- there are three -- there are three parts to
3 that question. The first one is the concept of
4 degradation. And if Prolene would degrade, all the
5 Burches that we did with polypropylene would
6 eventually fail. And all the -- and most of the
7 slings that we did with polypropylene would eventually
8 fail clinically.

9 And we know that the evidence points out
10 that that's -- that's not the case. That's the first
11 part of degradation.

12 Number two is polypropylene, the way it
13 defines degradation on a dog or in a rabbit or in a
14 Himalayan or a Wistar rat or a Himalayan -- Himalayan
15 rabbit, the way it's defined cannot be translated
16 to -- to a -- to a person because they're completely
17 different hosts and the stresses that are placed on --
18 on those implants are completely different.

19 The immunologic reaction is different and
20 the cellular level is different, cellular findings are
21 different. And, finally, is the concept that -- that
22 Prolene and -- would -- would degrade and create
23 anything beyond what the sling would create. No, they
24 stay -- they're both exactly the same, the same. Not

1 exactly, but they're both very similar implants.

2 So those are the three -- three aspects to
3 your question, and I know it's an extremely elaborate
4 answer for probably a much more straightforward
5 question. But there's -- the concept of degradation,
6 I would have to accept that concept to agree with
7 your -- with what you just presented.

8 Q. (By Mr. De La Cerda) I think step one is
9 we need to define what we're talking about by
10 degradation.

11 We know that in 1987 there was a study done
12 by Ethicon on explanted Prolene suture from humans;
13 right?

14 A. On explanted and not -- I believe it's from
15 the dog study.

16 Q. There is one of humans, too. Have you seen
17 that one?

18 A. No, I haven't -- haven't. I'm not aware of
19 that one.

20 Q. Okay. If there's a study from 1987 on --
21 and these are Prolene sutures explanted from humans,
22 if those show the cracking and degrading that's
23 indicative of degraded polypropylene, that's the kind
24 of degradation that I'm talking about.

1 A. Are you referring to the eye study?

2 Q. I'm sorry?

3 A. To the eye study. Are you referring to the
4 polypropylene being removed from the eye?

5 Q. Vascular -- I believe they were implanted in
6 the heart. Unfortunately, I didn't bring that study
7 with me. I assumed you would already be aware of it.

8 My understanding is they were explanted from
9 the hearts of the patients. They were Prolene sutures
10 explanted from the heart of human patients.

11 Are you aware of that one?

12 A. No, I'm not aware. I know there is a study
13 on blood vessels and I know that there is a study
14 of -- on the eye and I know about the dog study.

15 Q. Okay.

16 MR. SNELL: For clarification purposes, you
17 have -- maybe if you knew -- I can tell you -- I
18 know what the name of it is. I mean, if that
19 would ring a bell with him.

20 MR. DE LA CERDA: Professor --

21 MR. SNELL: Gudion, blood vessels.

22 THE COURT REPORTER: Can you spell that one?

23 MR. DE LA CERDA: I think it's G-u-d-o-i-n
24 or something like that. That's the professor's

1 last name.

2 Q. (By Mr. De La Cerda) Does that ring a
3 bell?

4 A. It's -- I am -- I read that. I do recall
5 reading it and I do recall that it was a very thin
6 polypropylene suture that was hand tied, but
7 there's -- I don't know how that translate to
8 degradation.

9 Q. (By Mr. De La Cerda) Okay. So the
10 finding in that study was at the surface, that there
11 was cracking on the surface of the suture; right?
12 And that when they tested the material from the
13 cracking, that it was indicative of oxidative
14 degradation to polypropylene; right?

15 MR. SNELL: I'm going to object on
16 foundation.

17 Go ahead.

18 A. I cannot confirm that, no.

19 Q. (By Mr. De La Cerda) Okay. Well, what
20 I'm trying to do is define the degradation I'm
21 talking about. And I think this is even in the
22 studies that discuss it, degradation, and there have
23 been in the studies discussion of the surface of
24 polypropylene has some sort of cracking that's going

1 on and when they look at that cracking, it's
2 believed to be polypropylene that's cracking and
3 degrading.

4 Now you've seen studies that have discussed
5 that issue; right?

6 A. I'm -- I'm aware of the paper by Clavé.

7 Q. Okay.

8 A. By one of the Clavés, by the way, not --

9 Q. Is there a brother, like an evil twin?

10 A. So I am aware of that paper and in that same
11 paper they cite the UV -- ultraviolet degradation, but
12 I am also aware that that paper was about normal
13 samples.

14 I'm also aware that the number of
15 low-density polypropylene study was less than -- I
16 believe it was a quarter of the sample and -- I don't
17 have to believe it, I actually have it here.

18 Q. You're welcome to pull out anything you'd
19 like to review.

20 What I'm trying to get at -- I'm just trying
21 to get us to agree at least on a definition of
22 degradation that I'm going to ask you about. And what
23 I'm trying to say is that's the version of degradation
24 I'd like to ask you about.

1 Now, I know you're already going to tell me
2 that's not clinically significant. I know you're
3 going to tell me it's not going to matter. I know
4 that. What I'm trying to first get is let's get an
5 agreement on that's the degradation I'm talking about
6 and then we can go through the -- to kind of finish up
7 the questions because you'll end up telling me that it
8 doesn't need to be in the IFU.

9 So focusing, first, on the degradation, the
10 version that I'm talking about is the cracking, the
11 surface cracking that happens of the polypropylene
12 that's at least been seen and reported on in some of
13 the studies. Is that version of degradation, is that
14 clinically significant or clinically relevant such
15 that it needs to be in the IFU for the TVT, TVT-O,
16 Gynemesh, Prolift and Prosima?

17 MR. SNELL: Objection, lacks foundation.

18 Go ahead.

19 A. The way it stands right now, with the
20 studies that I have seen, specifically the ones on --
21 in general polypropylene -- the ones on the eye, I
22 believe I saw that. The way it stands right now, that
23 type of degradation has not been shown on the -- on
24 actual samples of slings. It has been shown in

1 abnormal samples, not in slings that work or come --
2 or have the clinical results that we have seen on
3 reports and it have -- it have not been shown in
4 any -- any studies having a clinical impact.

5 Q. (By Mr. De La Cerda) Okay. What do you
6 mean by "abnormal slings"?

7 A. If there is a sling that has an exposure,
8 and especially slings that are exposed to a surface,
9 then that will be abnormal sample.

10 Q. Okay. Exposed to what kind of surface?

11 A. To the vagina or the bladder or the bowel.

12 Q. Okay. So is there something that's
13 happening during that exposure that -- that your
14 belief is causing this phenomenon of degradation?

15 MR. SNELL: Objection. Hold on.

16 Misstates -- I don't think he testified, Counsel,
17 that he believes in degradation. I think you're
18 taking what he said -- I think you're misstating
19 his answer.

20 Go ahead.

21 A. The -- what we see in abnormal slings is
22 that a biofilm is created and this biofilm is -- has
23 been seen in catheters, it has been seen in IUDs, it
24 has been seen in other implants that are exposed to

1 air.

2 Q. (By Mr. De La Cerda) Okay. So is that --
3 is that your explanation of what you believe is
4 actually being seen when we see this cracking?

5 A. That -- that is -- that is actually what --
6 what I see, the only correlation that I can put
7 together with the cracking.

8 There's no other explanation based on what I
9 know and what I have researched that mechanical stress
10 retrieval or a biofilm.

11 Q. Okay. We know -- well, you know that raw
12 polypropylene without any antioxidants would degrade
13 in the human body. Do you know that or no? Or do you
14 believe that or no?

15 A. No, there's no evidence that there's
16 degradation.

17 Q. Okay. Do strong oxidizers like peroxide, do
18 those affect raw polypropylene or no?

19 A. The only report that I was able to find on
20 it was in containers, which is different from this --
21 it's the same hydrocarbon, but different containers on
22 a surface outside.

23 Q. Okay.

24 A. Actual containers that were used for

1 storage. This is completely different from -- from
2 what is used in slings in prolapse. So there's --
3 it's a hypothesis. That's probably upgrading it to a
4 hypothesis.

5 Q. Ultimately you believe, though, that the
6 cracking that's seen when the studies are discussing
7 degradation is really a biofilm and not the
8 polypropylene itself; right?

9 A. I -- I don't know if it's the biofilm or
10 it's a matter of technique or if it's a stressor that
11 was placed on the sample on retrieval. We -- we don't
12 know that. And most -- most importantly, we know that
13 probably any -- regardless of the reason why it
14 happens, it doesn't translate in any physical outcome,
15 in a clinical significant outcome.

16 Q. What about the erosions, though? So you
17 mentioned that they were abnormal meshes that had
18 eroded and were exposed to air, isn't the fact there
19 is an erosion, isn't that some sort of clinical --
20 clinically significant event?

21 MR. SNELL: Form.

22 A. No, the exposed segment of the sling doesn't
23 mean that it eroded. The most frequently -- the
24 most -- normally, the most frequent reason why you see

1 an exposed sling or a mesh is because there's a bone
2 healing that -- the dehiscence of the wound, there is
3 a dehiscence of the wound, there is a disorder of the
4 wound healing.

5 So we have seen disorders of wound healing
6 in patients that have prolapse even before we place --
7 we replace it, and we actually have seen it with
8 sutures. Not only with polypropylene sutures, we have
9 seen it with polyester sutures, specifically, and we
10 have seen it with GORE-TEX sutures.

11 And there's actual clinical evidence that
12 shows these abnormal wound healing occurring on the
13 presence of these sutures, and also with native
14 tissue. So this is not that the sling work itself
15 around and erode. This is an incision that has been
16 open.

17 Q. (By Mr. De La Cerda) And is there any --
18 and what's responsible for the poor wound healing or
19 the wound healing issue?

20 A. There are a variety of factors. These are
21 defects in the fibromuscular layer, specifically, as I
22 place -- as I wrote in my report, loss of tensile
23 strength in the abdominal sutures that put the wound
24 together.

1 Number two, there are mechanical factors.

2 Number three, there are actual wound-healing
3 factors, such as immune disorders, poor tissue
4 healing, cigarette smoking, and finally hematomas,
5 just to mention a few.

6 And these conditions may predispose a wound
7 to open and expose the graft. It may predispose the
8 wound not to heal properly over a suture and it may
9 predispose the wound not to heal properly just over
10 native tissue.

11 Q. Have you -- are you aware of an exposure and
12 erosion ever happening not related to a wound healing
13 issue?

14 A. No, that's -- that's -- is a problem of
15 wound healing.

16 Q. And that's it?

17 A. And that's what I see consistently.

18 Q. But it's your belief that that's the only
19 reason why there might be an exposure or erosion is
20 because of wound healing; right?

21 A. It is the most viable factor of the three
22 fact- -- of the three -- of the interaction between a
23 graft on a host, is the most viable factor is the
24 host. And the -- the sling's consistent. Or the --

1 or the polypropylene is a consistent material. And
2 there's obviously the third one, which is the
3 insertion, the technique, but if you really look at
4 technique being constant, it's always a wound healing
5 issue.

6 Q. So one of the problems could be the doctor's
7 fault, the other problem could be the patient's fault
8 because of their body and their wound healing, but
9 third issue can't be the implant because it is what it
10 is and it's --

11 A. I would not simplify just with it being a
12 fault. We -- this is not -- these are not issues that
13 are just -- that just happened with -- with mesh.
14 We -- we know that these issues go way -- for any
15 prosthetic material, way back before any prosthetic
16 material. We know that these issues happen with
17 polyester sutures in uterosacral ligament suspensions.
18 We know that there are instances in which there has
19 been no mesh, there being a suture and the suture had
20 to be removed. And we know there are instances in
21 which we don't use a mesh at all and that incision
22 opens up. The most viable aspect is the host.
23 There's definitely a variation on the insertion
24 technique and I think that by now we all have evidence

1 that those with the most experience have the lowest
2 rate of -- lowest rate of problems. Not only this
3 surgery, any other surgery, but the most consistent
4 part is the prosthesis, the polypropylene.

5 Q. Do you believe that mesh degrading or
6 breaking down can lead to an erosion or exposure or
7 no?

8 MR. SNELL: Foundation.

9 A. There's -- there's no evidence that that's
10 the case.

11 Q. (By Mr. De La Cerda) Do you believe that
12 polypropylene can become brittle?

13 A. How -- how do we define brittle?

14 Q. That's a good question.

15 A. You're going to probably --

16 Q. What's your understanding of the term
17 "brittle"?

18 A. Brittle is weak. Brittle could be friable.
19 Decreased tensile strength to put it in exact terms.

20 Q. So using that explanation of what brittle
21 means to you, do you believe that polypropylene can
22 become brittle?

23 A. No.

24 Q. Okay. So now let's get to the question

1 about your opinion. Should Prolene's tendency to
2 degrade in the human body be included in the IFUs for
3 the TVT, TVT-O, Gynemesh, Prolift and Prosima?

4 MR. SNELL: Lacks foundation, misstates,
5 opinion testimony.

6 A. There's -- there's nothing to place the
7 result of degradation.

8 Q. (By Mr. De La Cerda) And your basis for
9 that opinion is what?

10 MR. SNELL: Asked and answered.

11 A. That degradation has not been defined in a
12 reproducible scientific way to have -- to be present
13 or, if present, to have any consequences in clinical
14 outcomes.

15 MR. DE LA CERDA: All right. I think that's
16 a good break point. It's 12:30.

17 (Thereupon, a lunch recess was taken from
18 12:30 p.m. until 1:20 p.m., after which the
19 following proceedings were held:).

20 Q. (By Mr. De La Cerda) All right. Doctor,
21 we're back on the record. There is one question I
22 wanted to ask you on the degradation issue.

23 If Prolene's tendency to degrade the human
24 body is clinically significant, clinically relevant

1 and statistically significant, should that information
2 be included in the IFUs for the TVT, TVT-O, Gynemesh,
3 Prolift and Prosima?

4 MR. SNELL: Objection, foundation, form.

5 Go ahead.

6 A. Any -- any significant clinical response
7 that deviates from what's reported in randomized
8 control trials should be -- should be a matter of
9 addressing it, regardless if there is a degradation
10 there underneath or not. And there -- there are
11 systems in place that allows for that reporting, more
12 than one system, actually.

13 Q. (By Mr. De La Cerda) So any risk or
14 complication that's clinically significant,
15 clinically relevant and statistically significant,
16 any risk or complication that's like that should be
17 included in the IFU, do you agree with that?

18 MR. SNELL: Form, foundation, misstates.

19 A. If there's -- anything that is clinically
20 significant, statistically significant, let's say we
21 have a voiding dysfunction that is higher than would
22 happen with a Burch procedure, if we have pain, any
23 type of an incidence of urge incontinence or urge
24 incontinence, incidents of any -- that should be

1 addressed. If it's different from the RCTs. But if
2 you're going to challenge what's reported on RCTs,
3 then you need to come up with a similar number of
4 patients and you need to have some statistical
5 validity to it.

6 Q. (By Mr. De La Cerda) Okay. Moving on to
7 a new issue and this one involves TVT and TVT-O.

8 What does cytotoxicity mean?

9 A. It means in the -- in experiment, the number
10 of cells that are not viable after exposure to an
11 agent is lower than the expected of the benchmark we
12 established.

13 Q. The definition you gave me, which, by the
14 way, is very accurate in a certain sense. It's funny,
15 so you told me exactly what the scientific definition
16 is. The other thing I was asking -- that I was
17 thinking in my mind is cytotoxicity, what does that
18 word mean, literally?

19 MR. SNELL: Form.

20 A. It means it will -- it means toxicity to the
21 cell.

22 Q. (By Mr. De La Cerda) Right. And you're
23 aware that the cytotoxicity assessment of the
24 Ulmsten Prolene polypropylene sling, using the ISO

1 elution method showed cell lysis and toxicity;
2 correct?

3 A. There was one other place, and I was able to
4 see that on company documents. There was one other
5 place in which they saw that there was a little
6 cytotoxicity, but when it was -- it could never be
7 reproduced, actually, when it was redone in the
8 agarose, in the agarose form, there was -- in the
9 agarose overlay method, it was not -- it was not
10 cytotoxicity.

11 And this is significant because the -- when
12 you do a drug elution test, essentially, you're
13 immersing the cells on a pool of this -- of this
14 polypropylene. It will be -- it's a huge amount.
15 It's an amount that you, on purpose, make it -- make
16 it toxic. The toxicity -- the toxicity is -- is
17 supposed to affect a lot more than this.

18 One of the biggest drawbacks of cytotoxicity
19 assays is that you cannot have a positive control. So
20 when you put agarose on it, you neutralize and you
21 make it more real. You neutralize it and make it more
22 real.

23 Q. In one of those two testing methods
24 cytotoxicity was shown; right?

1 A. It was in one plate. It was not
2 scientifically significant to it. When normal
3 polypropylene was -- was examined on L929 mouse
4 fibroblast cells, there was no cytotoxicity.

5 Q. Have you studied what happens to tissues
6 when it's exposed to a cytotoxic substance?

7 A. Yes, I have.

8 Q. And can you explain what those studies were?

9 A. Before going to OB/GYN, I did a fellowship
10 on molecular pharmacology, and I did a flow cytometry
11 and cytotoxicity assays, that's what I did every day.

12 Q. Okay.

13 A. And we use different agents. So there's --
14 one thing that we know that tissue configures a
15 protection different from cells. Tissue makes --
16 makes the viability of cells coming -- mediating by
17 whatever response that you may have to a cytotoxic
18 agent.

19 So far, and there has not been any evidence
20 that polypropylene is a cytotoxic in the muscle that
21 been by biopsy or by any other -- other test.

22 Q. Would you agree that necrotized tissue
23 surrounding mesh could lead to erosion or exposure of
24 the mesh?

1 A. If you see a necrotic tissue in an incision,
2 it's a wound dehiscence.

3 Q. So do you agree or disagree with that
4 statement -- or that question?

5 MR. SNELL: Form.

6 A. That -- you will have to repeat it. I'm
7 sorry.

8 Q. (By Mr. De La Cerda) Would you agree that
9 necrotized tissue surrounding the mesh could lead to
10 an erosion or exposure of the mesh?

11 A. If it's at the wound, yes, it can lead to
12 that.

13 Q. Should the cytotoxicity assessment of the
14 Ulmsten polypropylene sling showing cytotoxicity be
15 included in the TVT or TVT-O IFUs?

16 MR. SNELL: Form, misstates.

17 A. Once you have a pyrogenicity assays and once
18 you have a drug elution and agarose test, if your
19 testing is negative, you just submit it to the FDA.
20 It doesn't have to be included as cytotoxic because it
21 will be -- it will be inaccurate.

22 Q. (By Mr. De La Cerda) So the answer is no;
23 right?

24 A. No.

1 Q. And what would be your basis for that
2 opinion?

3 A. My -- the review of the -- the review of the
4 cytotoxicity assays that were made available to me
5 through company documents.

6 Q. Okay. And which ones were those?

7 A. The ones on TVT.

8 Q. And those included the ISO agarose diffusion
9 method?

10 A. That includes -- there are two types of
11 tests that were done. There was the agarose, the drug
12 elution, and pyrogenicity and to check for the
13 inflammatory reaction also of injected polypropylene.

14 Q. Any other bases for this opinion?

15 A. This is -- this is the basis for the
16 opinions.

17 Q. Do you know what the significance is of mesh
18 being heavyweight as opposed to lightweight?

19 A. There's -- there's -- the difference --
20 difference in weight -- in the weight, essentially.

21 Q. And it's really a description of density,
22 right, not actual mass?

23 A. It has -- it has to do with how much per a
24 square -- square millimeter is, how much does it weigh

1 in terms of grams per square millimeters.

2 Q. And so do you have an understanding of what
3 the significance in terms of risks and
4 complications --

5 A. I -- I misspoke.

6 Q. Okay.

7 A. I misspoke. It's not per square millimeter.
8 It is per square meter.

9 Q. Okay.

10 A. I can double-check that.

11 Q. Do you have any understanding of what the
12 significance is in terms of risks and complications
13 when you look at lightweight mesh versus heavyweight
14 mesh?

15 MR. SNELL: Form.

16 Go ahead.

17 A. The heavy -- heavyweight meshes with -- not
18 only just with the weight, but with all the other --
19 the other factors, including fiber size, pore -- pore
20 diameter, and method of coming together, either being
21 knitted or woven, had to do with the tolerability and
22 biocompatibility of the implant.

23 Q. (By Mr. De La Cerda) So let's get back to
24 my question, though. Is there a difference in terms

1 of risks and complications for a patient between
2 lightweight and heavyweight mesh?

3 MR. SNELL: Form.

4 A. Not to the point that has been clinically
5 demonstrated.

6 In theory, we could -- in theory, there is a
7 difference. In the lab, when we use large portions we
8 can infer that, but that has not been shown in the
9 clinical arena of incontinence.

10 Q. (By Mr. De La Cerda) Okay. So now --
11 okay.

12 First of all, let's discuss, what is the
13 theory of the difference -- the theory of the
14 significance as to risks and complications when you
15 compare lightweight versus heavyweight mesh?

16 A. It's the biomechanical behavior is
17 different. The biomechanical behavior is different
18 not only for that type of preparation, but it's also
19 different for the caliber of the sutures.

20 In other words, if I use a thinner suture,
21 that being polypropylene or any other material, it
22 will -- it can behave differently. It has a tendency
23 to behave differently than a lightweight mesh or a
24 heavyweight mesh.

1 Q. Okay. In what ways?

2 A. In the testing, when you stretch it, when
3 you fold it, when you place it and have fibroblast
4 growing along the lines of stress of the implant.

5 Q. Okay. What about in terms of foreign body
6 reaction, is there a difference between lightweight
7 and heavyweight mesh?

8 A. We used to believe that there was much more
9 on the heavyweight meshes, much more foreign body
10 reaction. But has been found is that that initial
11 reaction of the acute inflammatory -- of the acute
12 inflammatory process and eventually of the chronic
13 inflammatory process leads to the creation of
14 fibroblast.

15 What biomechanically has been concluded is
16 that that level of stress, the level of stress in
17 these implants, the level of tension or forces that
18 are applied to these implants, behave differently and
19 that seems to determine how fibroblasts grow.

20 So the heavyweight and the lightweight
21 behave differently. There has not been a single study
22 that shows, at a microscopic level, 80,000, 100,000
23 samples, but we do have clinical studies that show
24 that number of women. So in terms of the clinical

1 behavior, it's probably less difference than what we
2 could see microscopically. In terms of the acute
3 inflammatory reaction, the difference between
4 200-micron of fiber and a 300-micron fiber is probably
5 not that much.

6 Q. So do you disagree with the theory that
7 lightweight mesh is safer for patients than
8 heavyweight mesh for use in the pelvic floor?

9 MR. SNELL: Form.

10 Go ahead.

11 A. I think that's a very broad statement to say
12 lightweight meshes for sure are safer. That is a very
13 elementary statement that -- for much more complicated
14 issue.

15 Q. (By Mr. De La Cerda) Okay. Are you
16 familiar with Closterhofen, Clinga? Are you
17 familiar with Todd Heniford? Are you familiar with
18 these physicians' and scientists' opinions about the
19 safety of lightweight mesh versus heavyweight mesh?

20 A. I am familiar with their work.

21 Q. Okay. Do you disagree with their
22 conclusions about lightweight mesh being safer for a
23 patient as compared to heavyweight mesh?

24 A. I think that their --

1 MR. SNELL: Form, foundation.

2 Go ahead.

3 A. I think that their conclusions are very,
4 very hypothetical at best.

5 Q. (By Mr. De La Cerda) Okay. Would you use
6 standard Prolene in the correction of pelvic organ
7 prolapse?

8 A. We did. Actually, we didn't just use
9 Prolene, we use Mersilene. We used Marlex. We used a
10 variety of materials before this, before we actually
11 use it for slings.

12 We didn't use it for slings because by the
13 time that midurethral slings came in, we have that
14 200-micron -- actually 196-micron fiber with a pore
15 size of 1500, and it was -- it was something -- it was
16 something that we knew that would match the thinnest
17 sutures that we could use for a Burch.

18 Q. To be sure I've got an answer to that
19 particular question, though, the answer is yes, you
20 would use standard Prolene mesh in the surgical
21 correction of pelvic organ prolapse; is that right?

22 A. Yes.

23 Q. Okay.

24 A. I could consider using it. There are other

1 factors that may not lead me to use it, but the weight
2 of the mesh is not the only factor.

3 Q. So you would disagree with anyone that would
4 say that using Prolene mesh in the treatment of pelvic
5 organ prolapse is too dangerous and risky. You
6 disagree with that; right?

7 A. I would disagree with that, yes.

8 Q. Have you ever read the deposition of Jorge
9 Holste?

10 A. I may have read it and if I did, I probably
11 read it over a year ago.

12 Q. Head of the preclinical department of
13 Ethicon for 30 years, german guy, he opined that
14 Prolene mesh is heavyweight mesh.

15 Does that ring any bells?

16 MR. SNELL: Foundation on that one.

17 A. Prolene mesh, the way they classify is
18 heavy -- heavyweight mesh. There were a number of
19 materials that I'm aware that they work with and they
20 classify according to weight. From the engineering
21 point of view, that might be accurate. From a
22 surgical point of view, there are a lot of other
23 factors that have to be considered.

24 Q. (By Mr. De La Cerda) Okay. Do you agree

1 or disagree that heavyweight mesh causes greater
2 foreign body reaction than lightweight mesh?

3 MR. SNELL: Form.

4 A. There might have -- there could be in
5 existence something that says that increases the
6 number of neutrophils, but I have not found any -- any
7 utility on clinical care on predicting the behavior of
8 TVT.

9 Q. (By Mr. De La Cerda) So do you agree or
10 disagree with that statement?

11 A. I -- I could not agree or disagree with
12 that. That's so general and I would be speculating on
13 it.

14 Q. Okay. Do you agree or disagree that leaving
15 less mesh material in the patient's body is important
16 because it will reduce the amount of inflammation and
17 foreign body reaction?

18 A. That's --

19 MR. SNELL: Hold on. You have to give me a
20 chance to object.

21 Overbroad and incomplete hypothetical.

22 A. That's more than a scientific approach.
23 That's a very attractive approach. And that's -- as
24 surgeons, we don't always base what we do on -- on

1 science, but also on common sense backed by science.

2 And, yeah, if I can take care of something
3 with less mesh, I probably would be attracted to it.

4 On the other side, you need to respect as surgeons
5 that say, "Well, you know, I will use the full-length
6 sling because it has the longest evidence behind it."

7 So in that regard, you're using more material, but you
8 have more evidence behind it.

9 Q. (By Mr. De La Cerda) Do you agree or
10 disagree that reducing the inflammatory reaction of
11 the body will also reduce the risk of contraction or
12 shrinkage of the mesh?

13 MR. SNELL: Same objection.

14 A. We don't -- we don't know that and I could
15 not agree with something that, in general, as a
16 specialty, we don't -- we don't know.

17 The reduced inflammatory reaction may not
18 work for the best. There's a chain of events that
19 happens during the inflammatory process and that leads
20 ultimately to the creation of a fibroblast angle that
21 is what gives the support beyond the implant.

22 Q. (By Mr. De La Cerda) It's scarring;
23 right?

24 A. It is -- it is not a scar. Scar is the most

1 simplistic way of looking at it because a scar does
2 not have the same viscoelastic capabilities of tissue.
3 So you have to -- when you say a scar, it's not
4 necessarily a scar in the way that we see scars. It's
5 viscoelastically it's different.

6 That's why someone can urinate after they
7 have a sling placed and they don't have retention.
8 That's how someone can have normal flows, someone can
9 be continent, at the same time also can go and
10 urinate.

11 Q. Are you familiar with the term "fibrotic
12 bridging"?

13 A. I've heard the term "fibrotic bridging,"
14 yes.

15 Q. What's your understanding of that term?

16 A. It's the growth of a fibroblast from one
17 segment to the next.

18 Q. Do you agree or disagree that heavyweight
19 meshes induce more fibrotic bridging tissue reaction
20 causing more shrinkage during maturing of the
21 collagenous tissue?

22 MR. SNELL: Form, foundation.

23 A. I saw it described at one time. I didn't
24 see anything that could conclude it. I did not see a

1 paper that could conclude it. I'm welcome to look at
2 anything that says that fibrotic bridging is
3 significantly more. The first thing I would like to
4 know is how you're going to measure it.

5 Q. (By Mr. De La Cerda) Okay. So I guess
6 you don't have enough information to either agree or
7 disagree; is that right?

8 MR. SNELL: Object, misstates.

9 A. I have -- I have enough information to -- to
10 not agree or disagree with it. And that -- the
11 information that I have is that from one segment to
12 the other, just looking at two segments and the
13 fibroblast that grow between, at one point in time
14 that's not enough to make that conclusion, that
15 fibrotic bridging would cause contraction or
16 anything -- or anything similar like that.

17 There's -- in one of the papers that I gave,
18 there are two papers that I submitted today about the
19 effect of stress on fibroblast growth, and I think
20 that's more complete than fibrotic bridging.

21 Q. (By Mr. De La Cerda) So is it fair to say
22 that you disagree with that statement then?

23 A. I -- I cannot say one way or the other
24 fibrotic bridging. If I would have to commit to

1 agreeing or disagreeing with it, I think that fibrotic
2 bridging is, again, very hypothetical -- hypothetical
3 statement. I also believe that I can change my
4 opinion based on what I read.

5 Q. Okay. So as you sit here today, though, I
6 think -- I think what you're saying, as you sit here
7 today, is you would have to disagree because you
8 believe there's not enough evidence to support the
9 statement? I mean, is that what you're saying?

10 A. There's not enough evidence to support
11 fibrotic bridging. It's a concept that is
12 interesting. It's a concept that can be studied.
13 It's a concept that has to be taken into the context
14 of what -- how fibroblast grow under stress.

15 Q. Are you aware that Ethicon's own scientists
16 and consultants have opined that Prolene mesh, the
17 same mesh in the TVT and TVT-O, is heavyweight as
18 opposed to being lightweight?

19 MR. SNELL: Lacks foundation.

20 A. I -- I -- I haven't seen the opinion of each
21 one of them.

22 Q. (By Mr. De La Cerda) Okay. So you're not
23 aware?

24 A. I'm not aware.

1 Q. Should a discussion of whether Prolene mesh
2 is heavyweight be included in the IFUs for the TVT and
3 the TVT-O?

4 MR. SNELL: Form, foundation.

5 A. No, I don't think that -- I actually believe
6 that most doctors, if you tell them heavyweight --
7 about heavyweight and lightweight meshes, they have
8 had to be educated on it.

9 I know that the great majority of them are
10 probably going to look at me and say, "Okay, Jaime, so
11 you're telling me about heavyweight and lightweight
12 and all these different aspects, tell me how does this
13 translate in the care of my patients?" And I would
14 disagree with -- with any statement that makes
15 anything firm about heavyweights or lightweights
16 because the fact is that the model to a study have not
17 been found.

18 Q. (By Mr. De La Cerda) Okay. And so your
19 opinion is that it doesn't need to be included in
20 the IFU; right?

21 A. No, I don't think that has any -- any place
22 in the IFU.

23 Q. And your basis for that is what? I don't
24 want to put words in your mouth.

1 What would be your basis for not having to
2 include it in the IFU?

3 A. Number one, it's not evidence -- the concept
4 of whatever implications they may have clinically is
5 not evidence-based and, number two, there are no
6 clinical implications that you can attribute to it.

7 Q. Okay. Part of your report discusses the
8 MSDS. So you've reviewed the MSDS for the raw
9 polypropylene that goes into making the Prolene and
10 the TVT, TVT-O, Gynemesh, Prolift and Prosima?

11 A. I saw the MSDS about raw -- raw material.

12 Q. Right. You're familiar with what a Material
13 Safety Data Sheet is?

14 A. I learned about Material Safety Data Sheet
15 along the lines of this -- of this litigation.

16 Q. Okay. So you know that the Material Safety
17 Data Sheet states that raw polypropylene is
18 incompatible with strong oxidizers, such as peroxides;
19 correct?

20 A. I read that in the MSDS.

21 Q. And as a physician, you know that peroxides
22 are present in the human body; right?

23 MR. SNELL: Form.

24 A. I am not aware of anyone measuring the

1 levels of peroxide.

2 Q. (By Mr. De La Cerda) Well, as a physician
3 you know that the human body produces hydrogen
4 peroxide as part of the inflammatory process; right?

5 A. I just have not seen a quantitative assay of
6 it.

7 Q. Okay. So you know it happens, you just
8 don't know what quantitatively it amounts to; right?

9 A. I'm not aware of any quantitative study.

10 Q. And the implantation of the TVT, TVT-O,
11 Gynemesh, Prolift and Prosima causes an inflammatory
12 process; correct?

13 A. The inflammatory process being defined as a
14 cellular process.

15 Q. Should the fact that raw polypropylene that
16 goes into making the Prolene, the TVT, the TVT-O,
17 Gynemesh, Prolift and Prosima is incompatible with
18 peroxides according to the MSDS, should that
19 information be included in the IFU?

20 MR. SNELL: Form.

21 A. No, it should not be included and based --
22 no, it shouldn't be included.

23 Q. (By Mr. De La Cerda) You already know my
24 next question.

1 What's the basis for not including that
2 information?

3 A. No raw material is being asserted on humans.

4 Q. Okay. Anything else?

5 A. No.

6 Q. Okay. You're also -- you addressed this in
7 your report. You're also aware that the MSDS states:
8 "Polypropylene has been tested in laboratory rats by
9 subcutaneous implantation of disks or powder, local
10 sarcomas were induced at the site of implantation."

11 Do you recall that verbiage that's from the
12 MSDS?

13 A. From the MSDS.

14 Q. What does -- what does that verbiage mean?

15 A. It's a disk, it's a disk of basically raw
16 polypropylene. And the way I see it is there are two
17 factors to it. Number one, the size and the volume of
18 the polypropylene that's being inserted, in addition
19 to the nature of this polypropylene. I cannot speak
20 about this being even remotely similar to what we use
21 on -- on TVT-O and what we use in Prolene sutures
22 because there is not -- there has been no
23 chromatography, no crystallinity assays, no
24 temperature assays on any of this disk. So I don't

1 have that information available.

2 That being said, you can also consider --
3 you should also consider the host in which most of the
4 time is Wistar rats, Wistar rats or Himalayan rabbits.
5 I had the opportunity to work with Wistar rats. They
6 have a very, very peculiar immune system.

7 Q. When there is an indication that a substance
8 can cause cancer in animals, like rats, what does that
9 possibly indicate for humans?

10 MR. SNELL: Form, speculation.

11 A. It has very, very little implications unless
12 you are consistently prove that these causes -- causes
13 cancer.

14 Now, this is -- these are -- it's very
15 important to define that these are two different
16 materials. The raw preparations are different from
17 the preparations used in -- in sutures. They're two
18 different things.

19 Q. (By Mr. De La Cerda) Chronic inflammation
20 has been linked to cancer; hasn't it?

21 A. That's -- that's not even a theory. That's
22 a hypothesis, actually.

23 Q. Okay. If mesh -- strike that.

24 Ethicon -- I need to go back for just a

1 second.

2 You're aware of no test performed by Ethicon
3 to determine whether the surface cracking or
4 degradation, or whatever you want to call it, that's
5 been -- that is seen under -- under microscope of the
6 mesh, whether it's biofilm or whatever you believe it
7 is, you've never seen a test by Ethicon to determine
8 whether that particular characteristic is clinically
9 significant to patients; right?

10 A. No, there are only three reports that I'm --
11 that I'm aware of.

12 Q. Okay. And you're aware of no test by
13 Ethicon to determine whether the weight of Prolene
14 mesh causes more complications in patients in
15 comparison to lightweight mesh; correct?

16 MR. SNELL: Form, foundation.

17 A. There's no -- no basis to generate that --
18 that study.

19 Q. (By Mr. De La Cerda) What do you mean by
20 that?

21 A. No one has come out with the actual question
22 in terms -- in the question on the hypothesis of it or
23 the theory of it.

24 Q. Okay.

1 A. In other words, just because we think that
2 there's a scientific study that we can do doesn't mean
3 that that needs to be done.

4 Q. Okay. But Ethicon -- Ethicon, itself,
5 hasn't performed that study; right?

6 A. I -- I am -- I am not familiar with the
7 specific studies that they have performed on that
8 specific area.

9 Q. You're aware of no study performed by
10 Ethicon to determine whether polypropylene could be
11 linked to cancer; right?

12 A. I -- I am not familiar of that, but I know
13 about the dog study that -- in which they -- sutures
14 were evaluated at about eight years and there was
15 no -- no reported cancer that I'm aware of.

16 Q. Okay. You brought one study with you here.
17 I think it was a case report of cancer and
18 polypropylene. What was it? You mentioned it briefly
19 when we were looking through your materials.

20 A. It is -- the first case reported of a clear
21 cell carcinoma in the surrounding area to the -- to
22 the incision for the midurethral sling.

23 I also brought the response from two experts
24 to that specific case report.

1 Q. What did that study -- did that study have
2 some sort of conclusion about what might be causing
3 that clear cell carcinoma?

4 A. No, it does not have a conclusion. There's
5 a hypothesis and that's as far as they can get about a
6 hypothesis about inflammation, I believe.

7 Q. And so that's one discussion of inflammatory
8 process being at least hypothesized as being
9 responsible for this particular cancer; right?

10 A. Yeah, unfort- -- I don't want to say
11 unfortunately, it's not unfortunate. It's -- this is
12 not an actual study. This is a case report.

13 Q. Case report.

14 A. One case report. And as we have gone
15 through so many times today, the overwhelming data --
16 there are papers that -- there are articles that
17 describe the continued use of polypropylene in
18 midurethral sling with the incidence of cancer in that
19 population or the frequency of cancer in that
20 population being actually zero.

21 Q. Okay. So then the question about your
22 opinion, should this warning that's included in the
23 MSDS -- or this verbiage that's included in the MSDS
24 regarding the subcutaneous implant of disk or powder

1 where local carcinomas were induced at the site of
2 implantation, should that information be included in
3 the IFUs for the TVT, the TVT-O, Gynemesh, Prolift and
4 Prosima?

5 A. The answer is no, and the basis of that is
6 that is not relevant to the product that is being
7 implanted.

8 Q. Has -- are you aware of any studies that
9 Ethicon's done comparing the raw polypropylene with
10 the manufactured version that is actually implanted in
11 humans, any test of any kind?

12 A. Raw -- raw polypropylene is not used in
13 humans. Raw polypropylene is actually not even used
14 on containers. It has very -- it doesn't have an
15 actual use. It's raw material.

16 Q. And so you're aware of no studies, though,
17 where Ethicon's tested raw polypropylene versus the
18 finished manufactured product of any type; right?

19 A. No, I'm not familiar with any studies using
20 raw polypropylene.

21 Q. Okay. Shifting gears a little bit.

22 You agree that as a scien- -- a scientist or
23 a physician should not go into a research study with a
24 desire to achieve a specific result; correct?

1 A. I -- I -- I'll have to read that. If you
2 can be blinded to your study, that would be optimal,
3 but that's not possible in every -- in every design.

4 Q. So are you saying that a scientist in a
5 re- -- scientist and a physician -- it's okay for
6 that -- strike that.

7 It's okay for a scientist and a physician to
8 go into a research study with the desire to achieve a
9 specific result?

10 A. No, I think that the design of the study
11 would actually protect the study from any desire that
12 anyone could have.

13 Q. So should or should not the scientist and
14 the physician go into a study with the desire to
15 achieve a specific result?

16 MR. SNELL: Form, overbroad.

17 A. I don't -- I don't believe that anyone
18 should go into any study hoping or wishing for a
19 specific result. That's not what the methodology of a
20 science is for.

21 Q. (By Mr. De La Cerda) You agree that a
22 scientist and a physician should not design a
23 research project for medical publication with the
24 specific purpose of a single result; correct?

1 MR. SNELL: Form.

2 A. It's -- there's no science if you are trying
3 to get it or achieve a specific result.

4 Q. (By Mr. De La Cerda) You can't go into a
5 medical scientific research trying to answer a
6 question with any preconceived biases; right?

7 MR. SNELL: Form, overbroad.

8 A. There's -- we -- we have seen that there --
9 there's some preconceived biases, but they become
10 clearly evident.

11 Q. (By Mr. De La Cerda) But you shouldn't go
12 in with any preconceived biases, that's what you
13 shouldn't do; right?

14 A. You don't -- you don't do that as a
15 scientist.

16 Q. Right. Do you agree it's not ethical for
17 researchers performing clinical trials to be paid if
18 and only if the clinical trials have certain results?

19 MR. SNELL: Form, overbroad.

20 Go ahead.

21 A. I have no basis to judge anyone that has
22 good science, good knowledge, and to be compensated
23 for it.

24 Q. (By Mr. De La Cerda) No, and I -- well,

1 that's excellent, but my question is a little
2 different.

3 What I'm saying is whether you believe it's
4 ethical for researchers performing clinical trials to
5 be paid if and only if they produce a study with
6 specific results.

7 MR. SNELL: Same objection.

8 Q. (By Mr. De La Cerda) So not the fact
9 they're being paid, just the fact they only get paid
10 if you give me these results?

11 A. Well, it's -- you're going -- if I'm going
12 to acquire a product from you, and I'm going to make
13 an investment on that product, I'm going to pay you
14 based on what you show me with your -- with your
15 product.

16 Now, you can -- you can actually do that.
17 You can sell me a product that may not perform as I
18 expect, but if I try that product and I see that
19 consistently works in ways that are the same or better
20 as you present it, you can go back and say that was
21 not an issue there.

22 Q. Okay. So you can go back in time and say it
23 was okay, it wasn't unethical to do that?

24 A. It's -- you can go back in time and say it's

1 not a matter of ethical or not ethical. I know that
2 there was a truth -- a truthful interaction and that
3 what this physician or anyone in that calculating
4 innovation shows me was -- was real, was actually
5 accurate.

6 Q. Okay. You mean that you can at least agree
7 that that has a potential to create bias, doesn't it,
8 in the study?

9 A. I -- but you can -- you cannot put that on
10 the person that is trying to bring it in. There has
11 to be a level of -- of understanding and backtracking.

12 In other words, if you -- and I'm going to
13 allow myself to place an example. If you try to sell
14 me a medical device, I will have a hard time buying it
15 from you. But when -- if you try to sell me a legal
16 product, I might be more attracted to buy from you and
17 I might believe that you may deliver that legal
18 product.

19 That has nothing to do with science. I
20 deviated into what -- just to illustrate a point just
21 to answer your question.

22 Q. You're aware, of course, that Ulmsten was
23 the inventor of original TVT; right?

24 A. Yes.

1 Q. And you've seen the Ulmsten and Nilsson
2 studies that Ethicon tauts as long-term support for
3 their TVT line of slings; right?

4 MR. SNELL: Form.

5 A. They also wasn't just the inventor of the
6 TVT. At that time he brought the most innovative kind
7 of approach to incontinence. I mean, we -- we were --
8 until that time, we were doing continence procedures
9 in the urethrovesical junction, we were using sutures,
10 we were placing things under tension, we were using
11 absorbable materials that didn't work long term,
12 materials that were not pliable and they came up and
13 changed the way we were thinking about continence
14 care. Continence care became different because of
15 Ulmsten and Petros.

16 Q. (By Mr. De La Cerda) Getting back to the
17 question. You've seen the studies that Ethicon
18 touts as support for their TVT line of slings;
19 right? You've seen those, the Ulmsten/Nilsson
20 studies; right?

21 MR. SNELL: Form.

22 Go ahead.

23 A. I've seen the Ulmsten studies, I've seen
24 Nilsson, I've seen Falconer, I've seen Petros.

1 Q. (By Mr. De La Cerda) You've seen it in
2 the marketing materials for Ethicon that they
3 frequently site to those studies as being support
4 for the use of their slings; right?

5 A. For that -- for that specific use, yes.

6 Q. And you've relied on these studies to
7 support your practice of using the TVT line of
8 products; right?

9 A. I rely on that and I rely more than that on
10 large studies. And the fact is that it has been
11 reproduced over and over again.

12 Q. Did Ethicon ever inform you that Professor
13 Ulmsten's company, MedScan, the company that owned the
14 rights to the TVT, was promised \$400,000 if and only
15 if it produced a study with the TVT showing certain
16 results?

17 MR. SNELL: Form.

18 A. There's my interaction with -- or any
19 surgeon's interaction for that sake at that time,
20 would never get into that.

21 Q. (By Mr. De La Cerda) So you haven't heard
22 that?

23 A. No, I -- I saw -- I saw that as one of the
24 claims, through all these documents, but really

1 didn't -- didn't matter much to me.

2 Q. Okay. So that particular fact doesn't
3 matter to you?

4 A. No.

5 Q. Okay. Shifting gears a little bit. Should
6 a medical device company put profits above patient
7 safety?

8 MR. SNELL: Form, speculation.

9 THE COURT REPORTER: I'm sorry, form --

10 MR. SNELL: Form, speculation. Put
11 overbroad in there, too.

12 A. Safety and results bring you profits.

13 Q. (By Mr. De La Cerda) So is the answer no?

14 A. No.

15 Q. Should a medical device company rush a
16 product to market with the primary purpose being to
17 defend its market share?

18 A. There's -- when you have a good product and
19 you have enough market share, yeah, you want to make
20 sure that you keep it and you keep it with quality.

21 Q. So the answer is yes to that one?

22 MR. SNELL: Form.

23 A. On that one -- on that regard, on the
24 general form of that question, yes.

1 Q. (By Mr. De La Cerda) What clinical
2 studies were done of the TVT-O before it was
3 released onto the market?

4 A. There was -- there were a variety of
5 studies. There was the Mulberry study --

6 THE COURT REPORTER: The --

7 THE WITNESS: The Mulberry.

8 A. -- and there was -- there were cadaver
9 studies, and there were studies on outside-in
10 transobturator slings.

11 Q. Was one of the studies by de Leval?

12 A. By Delorme first and then de Leval.

13 Q. Delorme was outside-in; right?

14 A. Right.

15 Q. And then de Leval was inside-out?

16 A. Right.

17 Q. De Leval is considered the inventor of the
18 TVT-O; is that right?

19 A. Yes.

20 Q. And do you know whether the results of
21 de Leval's clinical studies were included in the
22 application for clearance submitted to the FDA for the
23 TVT-O?

24 A. I'm not familiar with what was exactly

1 submitted. I cannot recall it right now. I can go
2 back and check what was submitted, but I'm not
3 familiar with it.

4 Q. If he had performed a study, do you believe
5 that that study should have been submitted along with
6 the information about the TVT-O to the FDA?

7 MR. SNELL: Form, calls for regulatory
8 opinion, outside the regulatory scope.

9 A. I think it goes to whatever -- whatever the
10 FDA feels that it requires from the company or
11 whatever the company fulfills in its obligations to
12 the FDA.

13 Q. (By Mr. De La Cerda) How about you as a
14 physician, before you're going to use a product,
15 would you want to know all the clinical studies that
16 are out there about that product before you start
17 implanting it?

18 A. I actually gave -- I have given testimony
19 today that I trust that the FDA is going to do what's
20 best in that regard.

21 Q. Do you have any understanding of what the
22 clearance process involves, 510(k) clearance?

23 A. Yes. I do have an understanding of it.

24 Q. Do you know whether the FDA requires

1 clinical studies before a product is 510(k) cleared?

2 A. I think that they have made -- I don't
3 think, I'm aware that they have made a decision to put
4 in place a mechanism that works exactly with a 510(k).

5 Now, am I someone to criticize or favor --
6 or favor that? I probably could sit in my big chair
7 and decide that, but the reality is that there's
8 people with expertise in regulatory affairs at the FDA
9 and people with expertise on regulatory affairs at
10 Ethicon, and they're the ones that need to come
11 together on that.

12 Q. I guess the issue that I'm really asking
13 about is what you want to know as a doctor. Before
14 you ever implant a product, do you want to know that
15 if there are clinical studies on that product before
16 you've implanted it, do you want to know what those
17 clinical -- what the findings were of those clinical
18 studies before you implant the product?

19 A. I'm aware of clinical products and design.
20 I'm aware of these studies, but you can present all
21 these studies and one final part is going to be what
22 the FDA regulatory process comes -- comes and tells
23 me.

24 Q. What I'm saying, though, is you, as an

1 implanting physician, okay, a product is presented to
2 you by a medical device company and there are clinical
3 studies out there that are about this particular
4 product. You're going to want to know all the
5 clinical studies that are out there about that product
6 before you implant it; right?

7 MR. SNELL: Form, asked and answered.

8 Go ahead.

9 A. I want to know -- I want to know the studies
10 and I want to know -- obviously, I want to know more
11 than just the studies. I want to know the
12 biomechanics of it, I want to know all these things.
13 But that's -- ultimately, it comes down to that
14 process between the -- between Ethicon and the FDA.

15 Q. (By Mr. De La Cerda) Okay.

16 A. And I'm going to trust the product that
17 comes out from it.

18 Q. Okay. Let's shift gears a little bit.

19 You're aware that the IFUs for the Gynemesh,
20 Prolift and Prosima state: "The mesh remains soft and
21 pliable and normal wound healing is not noticeably
22 impaired"; right?

23 MR. SNELL: Foundation on that.

24 Do you have that IFU? I'm not sure if you

1 made a correct statement across all those IFUs.

2 Do you mind taking a break?

3 MR. DE LA CERDA: That's fine. Let's do

4 that.

5 (Thereupon, a recess was taken from

6 2:11 p.m. until 2:18 p.m., after which the

7 following proceedings were held:)

8 Q. (By Mr. De La Cerda) Doctor, just for the
9 sake of showing you, this is the Gynemesh -- sorry,
10 I didn't bring a copy of it -- so that's the
11 Gynemesh IFU. The part that I'm referencing is at
12 the bottom, I think it's the second-to-last
13 sentence. It starts with "the mesh remains
14 pliable."

15 MR. SNELL: Soft and pliable.

16 Why don't you ask him to read it just so the
17 record is clear.

18 MR. DE LA CERDA: Yeah, sure.

19 Q. (By Mr. De La Cerda) Can you read that,
20 Doctor?

21 A. "The mesh remains soft and pliable and
22 normal wound healing is not noticeably impaired. The
23 material is not absorbed, nor is subject to
24 degradation or weakening by the action of tissue

1 enzymes."

2 Q. (By Mr. De La Cerda) So that statement is
3 included, of course, in the Gynemesh IFU and the
4 Prolift and Prosima IFUs, which also use Gynemesh;
5 right?

6 A. Yes.

7 Q. Now, you're aware that Gynemesh PS is
8 Prolene Soft, except for it's used in the pelvic
9 application as opposed to hernia application; right?

10 A. It's -- Pro- -- Prolene Soft, yes.

11 Q. Are you aware that in 2001, Ethicon had in
12 its files a conclusion that Gynemesh PS was too stiff
13 for use in vaginal tissues?

14 MR. SNELL: Form, foundation.

15 A. It's -- I read something about that from
16 some investigator, but it was -- it was an opinion
17 about being too stiff. I think it was at the -- at
18 the risk of -- I'm not remembering well or -- I'm not
19 speaking accurately, may have been an investigator's
20 opinion.

21 Q. (By Mr. De La Cerda) Okay. Are you aware
22 that Ethicon also had in its files a conclusion that
23 Prolene Soft should not be pursued as a mesh used in
24 pelvic floor repair because it was too stiff for use

1 in vaginal tissues?

2 MR. SNELL: Same objection.

3 A. No, I'm not -- I'm not aware of that and
4 that's not what was eventually done.

5 Q. (By Mr. De La Cerda) Do you know whether
6 scar contracture around the mesh can occur with the
7 Gynemesh?

8 A. There's -- there's -- there's this -- again,
9 hypothesis that scar contraction could happen around
10 the mesh. So to that -- to that specific issue, I ask
11 what is the objective measurement of a scar
12 contraction or the mesh contraction. I wanted to see
13 where -- where's the evidence to it?

14 Because when we repair these -- repair these
15 patients with permanent sutures, when we place
16 polypropylene in the uterosacral ligaments or in the
17 sacrospinous ligament, we didn't see any contraction
18 of those fibers. So where is the evidence? No one
19 could ever bring me evidence of a contraction on the
20 mesh.

21 Q. Okay. Do you know if that -- if this scar
22 contracture around Gynemesh was a problem that Ethicon
23 engineers were trying to solve?

24 A. I -- I don't even know if they try to solve

1 it because I did not see a problem with contraction.

2 Q. Okay. So you're also not sure, though,
3 whether Ethicon was trying to solve this problem? You
4 probably don't believe it's a problem. That's what it
5 sounds like you're saying, that it's not a problem,
6 but my question is really are you aware whether
7 Ethicon was trying to solve what it perceived to be a
8 problem with contracture of scar tissue around
9 Gynemesh?

10 MR. SNELL: Foundation.

11 A. I don't -- I don't see in which model they
12 would try to solve it.

13 Q. (By Mr. De La Cerda) Okay. But are you
14 aware if they were trying to solve this or not?

15 A. No, I'm not aware of them trying to solve
16 contractions of any -- any type, any type of implants.

17 Q. If scar contracture exists around Gynemesh,
18 would that translate into complications for a patient?

19 MR. SNELL: Form.

20 A. More than a complication for a patient. The
21 contraction would just tell me that I have to -- I
22 have to make adjustments in my surgery and that brings
23 a whole new set of variables in my -- in my surgery.

24 Q. (By Mr. De La Cerda) Do you know whether

1 or not physicians were asking Ethicon for a mesh
2 which would be better than Gynemesh on the issue of
3 scar contracture?

4 A. I -- I believe that there was always the --
5 the idea that we could always have innovation on the
6 type of implants that we would have. Although
7 Gynemesh had more evidence than any other implant.
8 There was more evidence, there are more papers
9 published on Gynemesh than native tissue for specific
10 compartments. We have that. We all -- we all did
11 have an understanding that there was going to be a
12 progression on the innovation of the product. So if
13 there is a course to do that, that's -- that's
14 something that I think every physician would want to
15 see.

16 Q. And Ethicon did that -- they did just that,
17 didn't they?

18 A. They -- they actually invited me and give
19 me -- with other doctors, tell me what -- what this --
20 what would you like to see in -- in the next
21 generation.

22 Q. They innovated so well that they even
23 developed a mesh, other than Gynemesh, that they
24 thought was safer than Gynemesh; right?

1 MR. SNELL: Actually, hold on. Objection,
2 foundation, misstates company intent.

3 A. I don't -- I don't think that that's what
4 they concluded, that it was safer. I don't think that
5 there is anyone that actually came and say, "Okay,
6 this is safer," or, "We have more evidence to say that
7 it's safer, but you may have to adjust it," or "It may
8 not contract or they will contract." I don't -- I
9 don't think it got to that point. I think that we had
10 what we had with Gynemesh.

11 Q. (By Mr. De La Cerda) Okay. Did you ever
12 do a presentation on the benefits of lightweight
13 mesh over heavyweight mesh?

14 A. I did make presen- -- many presentations on
15 how -- on the benefits of lightweight mesh, and that
16 was a prevailing -- the prevailing thought at that
17 time and I still would make a presentation and say
18 there are some benefits on lightweight mesh. There
19 are -- there's some benefits on having less implant,
20 in having less mesh.

21 The question is when we have all this -- all
22 these different -- different things that we wish for,
23 how much science do I have behind it? And during
24 those -- those presentations, there's always the

1 discussion of: Is this really what we want? Do we
2 want bigger pores? Do we want a lighter --
3 lightweight meshes? Do we want lighter meshes?

4 I'm not saying that it's going to be a bad
5 thing. It's probably going to be a good thing, but I
6 don't have the science to back it up.

7 Q. You mentioned that you did present on some
8 of the benefits of lightweight mesh or using less
9 mesh. What would those benefits be?

10 A. It's a -- the benefits is that you have less
11 inflammatory response, you have less cellular
12 response, you have a better layout of fibroblast and
13 that's the hypothesis behind all this.

14 But none of those things that we, as a
15 group, thought as -- as physicians thought that was
16 going to be better, wasn't necessarily going to be
17 better. These were things that were not statements.
18 These were things that we have it here and we have
19 this product and it's worth looking to it and it's
20 worth using it and, you know, if I'm going to have --
21 use something heavier or something light, I probably
22 go with something light because it's more innovative.

23 Q. It's a reasonable theory to believe that the
24 lightweight mesh is safer for a patient than the

1 heavyweight mesh; right?

2 A. No. That's not --

3 MR. SNELL: Lacks foundation.

4 Go ahead.

5 A. No. That's not what we can conclude with
6 it. We're not talking -- Gynemesh proved to be safe.
7 Gynemesh proved to be effective. This is a totally
8 different set of considerations, scientifically it's a
9 totally different set of considerations.

10 Q. (By Mr. De La Cerda) Let's do it this
11 way. What I want to do is work from possibility all
12 the way up to truth. Okay?

13 Possibility, hypothesis, theory and we'll
14 just say reality or truth. Okay?

15 Is it possible -- do you agree it's possible
16 that lightweight mesh is safer for patients than
17 heavyweight mesh?

18 MR. SNELL: Calls for speculation.

19 A. That's -- that's possible.

20 Q. (By Mr. De La Cerda) Okay. Now let's
21 take the next step.

22 Would it be a fair hypothesis that
23 lightweight mesh is safer than heavyweight mesh?

24 A. That's a hypothesis, period. Not fair, not

1 unfair, it's just a hypothesis that we would have to
2 test.

3 Q. Okay. Is it a fair -- based on what you
4 know, is that a hypothesis that could be confirmed?

5 A. Well, that's a hypothesis that has much less
6 evidence behind it than -- than using Gynemesh.

7 Q. The step where you would stop the
8 progression, though, would be a theory. You don't
9 believe there's enough to support the theory that
10 lightweight mesh is safer for patients than
11 heavyweight mesh; is that right?

12 A. These were -- these were considerations that
13 were entertained not at that time. They still
14 entertain a scientific meeting. It doesn't mean that
15 we're going to go -- go out and start using the
16 lightest weight mesh. It doesn't mean -- because we
17 understand meshes a lot better now as -- as
18 physicians. As surgeons, as scientists, we understand
19 it better.

20 Now, we knew that what we had would -- would
21 give durability. We knew that what we had would
22 give -- would be a good product to use for
23 reinforcement on augmented repairs. There was --
24 there was some concept along the lines that were not

1 as explored as is being explored now. And based on --
2 on those concepts that were unexplored, we made
3 inferences on how we would like the next mesh to be.

4 That doesn't take the fact that what we had
5 behind us was data from Gynemesh.

6 Q. Do you agree that scar contracture can cause
7 recurrence of prolapse? This is in terms of if scar
8 contracture is happening around Gynemesh, can that
9 cause recurrence of prolapse?

10 MR. SNELL: Foundation.

11 A. Are you talking about the same side or
12 opposite side or just in general?

13 Q. (By Mr. De La Cerda) In general.

14 A. No, that's not the biggest factor on a
15 recurrence of a prolapse.

16 Q. I'm just going to go through a little list
17 right here.

18 Do you agree that scar contracture around
19 Gynemesh can cause pain?

20 A. Contractions of scarring always have the
21 potential to decrease the pliability of not only a
22 mesh augmented repair but of any -- any repair.

23 Q. That was actually going to be my next
24 question.

1 First of all, the pliability can lead to
2 pain? Like reduced pliability can lead to pain in a
3 patient; is that right?

4 A. If there's less pliability and there are a
5 number of factors to -- for a repair being less
6 pliable, but if there is less pliability and the
7 tissue is placed under -- under stress, yeah, you
8 would -- you would feel more that it would be more
9 pliable.

10 Q. Could the scar contracture lead to erosion?

11 A. No.

12 Q. How about discomfort during sex?

13 A. Less, less pliability could make things feel
14 not -- not as soft, not as elastic.

15 Q. Would you agree that for a mesh to be
16 successfully used for the treatment of pelvic organ
17 prolapse it should be soft and compliant with a
18 woman's vaginal tissues?

19 A. And that is -- that is an excellent question
20 because I would like to define, which I didn't have to
21 define before in the medical arena, I didn't have to
22 define as much what soft and pliable and elastic is.

23 I have tried to come to -- to the conclusion
24 that there is a level of the formation of stress that

1 is required. You cannot have so much deformation that
2 the prolapse comes out, but you still have to have
3 some firmness to your repair. In other words, you
4 drive your car, you need your shock absorbers to give
5 some give, to give some, but you don't want your shock
6 absorbers to be bouncing all over the place. It would
7 be as uncomfortable as no bouncing at all.

8 So when I -- when I take my car for a shock
9 absorbers check, they have something that actually
10 measures it and they can adjust it. They can adjust
11 the damper and give. We don't have that in the
12 vagina.

13 Q. Ethicon certainly never tested that issue;
14 did they?

15 MR. SNELL: Objection, lacks foundation.

16 A. The vaginal pliability, I think that there
17 was some papers about designing a device -- there was
18 a paper, actually, Dr. Willy Davila, I believe, was
19 testing a device for vaginal pliability; and that
20 would be very useful in getting an actual number,
21 getting an actual measurement that we can take from.

22 Q. (By Mr. De La Cerda) Is that something
23 that Ethicon did?

24 A. No, I think -- I don't think -- I'm not

1 aware of Ethicon doing that.

2 Q. Would you agree that clinically there may be
3 an impact of increased rigidity with any given mesh as
4 it may increase vaginal stiffness post-operatively
5 with a potential to impair sexual function?

6 A. I -- I misspoke on my last answer. I want
7 to correct that.

8 When I say Ethicon never -- never did that,
9 I cannot conclude that because I'm not aware if they
10 did or if they didn't, but I'm just -- that's what I'm
11 aware of, that I don't know if they did or didn't.

12 Q. That's fair.

13 Let me go back to my question, the next
14 question. Would you agree that clinically there may
15 be an impact of increased rigidity with any given mesh
16 as it may increase vaginal stiffness post-operatively
17 with a potential to impair sexual function?

18 MR. SNELL: Form, speculation, incomplete
19 hypothetical.

20 A. There's -- the papers that we have does
21 not -- does not suggest or indicate rigidity. If
22 there is a shrinkage or rigidity, it was not
23 demonstrated on the measurements of total vaginal
24 length. When you measure total vaginal length, not on

1 one but in two, three studies with comparing different
2 repairs and native tissue repairs to mesh augmented
3 repairs, the vaginal length stays exactly at the
4 same -- at the same length.

5 Q. (By Mr. De La Cerda) Should Ethicon's
6 conclusion -- strike that.

7 Should information about the concerns of
8 physicians and at least some within Ethicon that
9 Gynemesh was too stiff or too rigid for vaginal
10 tissues, should that information be included in the
11 IFU or no?

12 MR. SNELL: Form, asked and answered.

13 A. No, I don't think that it needed to be
14 included and the fact is that surgeons have the
15 options of doing augmented repairs or doing --
16 continue doing native tissue repairs. And they will
17 have whatever concern they may have with one or the
18 other, they have the option of doing one or the other.
19 No one mandated to do a mesh repair or a native tissue
20 repair at a certain time. But if you went by the data
21 and went by the durability and went by the evidence
22 about -- with Gynemesh, you have -- you were empowered
23 with information to decide one way or the other.

24 Ethicon does not tell surgeons who --

1 actually, they never told me, I can tell you that, and
2 they would never tell anyone, "You have to do this
3 repair with this type of material." And I don't think
4 they would include that in the IFU and they would not
5 include that on any communication because it's up to
6 the surgeon to decide that.

7 Q. (By Mr. De La Cerda) So would that be the
8 basis for why that information is not -- does not
9 need to be included in the IFU, according to your
10 opinion?

11 A. If the information on the -- on the IFU has
12 to do with the product itself and if there's no
13 evidence of the product performing one way or the
14 other, I would not expect anyone to misrepresent it
15 one way or the other. In other words, I don't --
16 don't misrepresent it saying that it performs better,
17 don't misrepresent it saying that it performs worse.
18 Just give me what the evidence shows.

19 Q. Would you agree that any future meshes
20 developed by Ethicon for pelvic organ prolapse should
21 be less rigid than Gynemesh?

22 A. I don't -- I don't know if it's going to be
23 any development, I don't know if it's -- it's going to
24 be on the same rate of damage. I think that --

1 THE COURT REPORTER: On the same?

2 A. On the same rate of -- on the same rate
3 of -- when I say "rate," on the same elasticity or
4 pliability of Gynemesh.

5 I don't know if it's going to be the same
6 stiffness or not. I just don't know what they're
7 going to do with the next generation.

8 Q. But my question is, though, is: If they are
9 going to develop the next generation, do you agree
10 that that next generation should be less rigid than
11 Gynemesh?

12 MR. SNELL: Objection, foundation.

13 A. I think we will have to first establish a
14 way of rigidity in -- once in the vagina and not just
15 on the testing that we have, biomechanical testing.

16 We know that biomechanical testing as
17 accurate and as elaborate and as complicated as it can
18 be, it doesn't always predict the -- the rigidity in
19 the vagina, because we don't know how to measure
20 rigidity in the vagina. We don't know how you're
21 going to measure it.

22 Q. Let me shift gears a little bit.

23 Okay. You understand before a medical
24 device can be marketed in the United States, the FDA

1 requires that the device receive some level of
2 clearance or approval before that marketing happens;
3 right?

4 A. Yes.

5 Q. You're aware that Prolift wasn't cleared for
6 marketing in the United States by the FDA until
7 May 15, 2008; right?

8 MR. SNELL: Form.

9 A. There were some -- some dates in there, but
10 I don't have the dates complete.

11 Q. (By Mr. De La Cerda) You understand that
12 Prolift was marketed in the United States for
13 approximately three years before it received
14 clearance. Do you understand that?

15 MR. SNELL: Form, foundation.

16 A. Yeah, it's -- it may have been marketed,
17 yes. I don't -- I don't know -- I cannot give you an
18 accurate answer on that.

19 Q. (By Mr. De La Cerda) Should the fact that
20 Prolift wasn't cleared for marketing in the United
21 States been included in the Prolift IFUs in place
22 prior to May 15, 2008?

23 MR. SNELL: Form, foundation, misstates the
24 regulatory --

1 A. Marketing -- marketing a device -- marketing
2 a device doesn't mean that you cannot -- you cannot
3 sell it. I don't think it has the relationship of one
4 with the other. If you -- if marketing means someone
5 visited me and giving me a brochure and telling me all
6 these things about the product, I really want to look
7 at the evidence. I will be courteous and I will
8 listen to it, but I will go to -- with the evidence.

9 And the evidence was, at that time and still
10 today, that -- that the materials used were as good as
11 a native tissue and was more durable.

12 Q. (By Mr. De La Cerda) So you're telling me
13 that doctors didn't need to know before they put in
14 a Prolift if it hadn't even been cleared by the FDA
15 until May 15, 2008?

16 MR. SNELL: Same objections.

17 Q. (By Mr. De La Cerda) Because there
18 were -- there were hundreds, if not thousands, of
19 Prolifts put in before it was ever cleared. Do you
20 understand that?

21 MR. SNELL: Same foundation, objection.

22 A. I'm not -- I'm not aware of that specific --

23 Q. (By Mr. De La Cerda) We can -- we don't
24 even have to have a number. If one was put in

1 before it was ever cleared by the FDA, do you think
2 it's okay for a doctor to not know that it wasn't
3 cleared by the FDA before he puts it in to a
4 patient?

5 MR. SNELL: Same objection.

6 A. It had a 510(k) approval; correct?

7 Q. (By Mr. De La Cerda) May 15, 2008. So
8 for three years it didn't.

9 Have you ever seen the correspondence
10 between Ethicon and the FDA about that clearance
11 issue?

12 MR. SNELL: Same objection, foundation.

13 A. I'm not aware of that, no.

14 Q. (By Mr. De La Cerda) Are you aware of the
15 510(k) being rejected a couple times?

16 MR. SNELL: Actually misstates the evidence,
17 foundation as well.

18 Q. (By Mr. De La Cerda) You haven't seen any
19 of that correspondence?

20 A. Not -- not on that specific issue, no, I
21 have not seen it.

22 Q. All right.

23 A. But if you give it to me, I'll check it out.
24 I'll give an opinion on it. That's -- that's ...

1 Q. So let's take the simple fact this product
2 was marketed in the United States before it ever had
3 clearance. Now, before a doctor ever implants the
4 product, do you think it's fair for him not to know
5 that the product he's implanting hasn't even been
6 cleared by the FDA?

7 MR. SNELL: Same objection, misstates the
8 evidence and the foundation as to the clearance.

9 A. If it's -- I don't want to give you an
10 opinion on something that I haven't seen.

11 Q. (By Mr. De La Cerda) As you sit here
12 today, you have not reviewed any of the
13 correspondence between the FDA and Ethicon regarding
14 the clearance of the Prolift under the 510(k)
15 process; right?

16 A. I -- I know that Prolift was cleared and I
17 know that there was -- the product had been sold. I
18 just don't know the specifics of when was it cleared
19 and the dates as you're referring to.

20 Q. What I want to try to get at now is, as you
21 sit here today, are you going to provide any opinions
22 about the Prolift and the timing of its clearance and
23 what effect that might have on warnings to doctors?

24 A. As we sit here today, I cannot give you an

1 opinion about something that I have not read.

2 Q. Okay. And so you know today is my
3 opportunity to question you about this issue. This
4 isn't a new issue, it's been around since 2008. So if
5 you're telling me today that you don't have -- you're
6 not prepared to provide an opinion on that issue,
7 that's great. That sends me down one road.

8 If you're telling me today that you do have
9 an opinion, then that's why -- then I would like to
10 ask questions about it. But if you're not going to
11 opine -- if you don't intend to opine on the effect of
12 the timing of the clearance of the Prolift through the
13 510(k) process and that effect on what should be
14 warned or what should be told to doctors about the
15 Prolift, then that's fine and we can move on to the
16 next subject.

17 A. No, I can -- I can look at those papers and
18 I cannot give you an opinion at this time about papers
19 that I have not seen.

20 Q. Are those papers in your Reliance List?

21 A. No, I don't think they're in my Reliance
22 List. If they would be, I would have read it.

23 THE WITNESS: Oh, you didn't --

24 MR. DE LA CERDA: I'm actually the nice one.

1 Out of all the plaintiff's guys you meet, I'm the
2 nice one.

3 MR. SPARKS: Hey.

4 MR. DE LA CERDA: He's a nice one, too.

5 Q (By Mr. De La Cerda) Let's switch gears a
6 little bit.

7 Do you agree with the FDA's viewpoint that
8 there is a need for more rigorous studies regarding
9 the safety and efficacy of transvaginal mesh kits?

10 A. The --

11 MR. SNELL: Hold on. You said -- can you
12 read that last -- he said transvaginal --

13 THE COURT REPORTER: Mesh kits.

14 MR. SNELL: I'm going to object, overbroad,
15 to the extent you're including Prolift
16 midurethral slings.

17 MR. DE LA CERDA: And I'm not, so I do want
18 to be clear about that.

19 When I'm using this term "transvaginal mesh
20 kits," it's transvaginal mesh for the correction
21 of pelvic organ prolapse.

22 So let me go back. Let me read the question
23 one more time.

24 Q. (By Mr. De La Cerda) Do you agree with

1 the FDA's viewpoint that there is a need for more
2 rigorous studies regarding the safety and efficacy
3 of transvaginal mesh kits, meaning transvaginal mesh
4 for the correction of pelvic organ prolapse?

5 A. No, I disagree with that recommendation.

6 Q. (By Mr. De La Cerda) Okay. And why is it
7 that you disagree?

8 A. I disagree because there was a wealth of
9 data on -- on the use of transvaginal mesh that has
10 been determined by more than 400 surgeons -- 400
11 active surgeons that it was adequate.

12 The decision of the FDA, with all due
13 respect to the organization or to whoever put the time
14 and put their effort in sitting on that committee, did
15 not -- did not translate on or did not convey the
16 experience of all the surgeons.

17 Q. Did you ever actually see the FDA's 522
18 orders that were issued with regard to Gynemesh,
19 Prolift and Prosima?

20 A. I did -- I did read about those, yes.

21 Q. Do you know what these orders required of
22 Ethicon?

23 A. Yes. I -- I read about the requirements and
24 I also read at one time the response of Ethicon to the

1 FDA.

2 Q. That was my next question. Do you know what
3 is it that Ethicon did in response to the 522 orders?

4 A. They -- they made a statement along the
5 lines of what I just mentioned, that there were
6 studies, not only RCTs, not only -- but also cohort
7 studies that show the benefits in durability, it
8 showed the safety profile, it showed risk and
9 complications, very well delineated in ways that no
10 other repair had been addressed.

11 Q. Did you also see any information regarding
12 Ethicon's estimate on the cost to have complied with
13 the 522 orders?

14 A. I did not see the exact cost, but I know
15 that any -- any study is costly.

16 Q. And Ethicon ultimately decided not to
17 perform what was discussed within the 522 orders;
18 correct?

19 A. That's -- that's what I -- I -- I saw from
20 the -- from that process, from that specific process.

21 Q. Ultimately, Ethicon decided to pull those
22 products from the market; right? Prolift and Prosima
23 were pulled from the market; correct?

24 A. Yes.

1 Q. And then Gynemesh, the indication was
2 changed from -- well, I guess before there were two
3 indications, then they changed it to just one. So now
4 the indication for transvaginal implant was removed
5 and now it's just abdominal sacrocolpopexy; is that
6 right?

7 A. That's correct.

8 MR. SNELL: I'm going to object. Wait.
9 Wait.

10 THE WITNESS: Okay.

11 MR. SNELL: Objection, foundation, misstates
12 the evidence and the clearance.

13 So go ahead.

14 Q. (By Mr. De La Cerda) So that's -- is that
15 your understanding of what was done is that Prolift
16 and Prosima were pulled from the market but Gynemesh
17 wasn't, just its indication was changed?

18 MR. SNELL: I'm going to have to object. I
19 didn't hear "pulled from the market." Same
20 objection, misstates the evidence.

21 If you take my basis, I'm sure you can get a
22 clean question and answer.

23 Q. (By Mr. De La Cerda) What I'll do is I'll
24 ask it this way: When Ethicon invented a word

1 called "decommercialization" and labeled that as
2 what it did for the Prolift and the Prosima, point
3 is ultimately Prolift and Prosima they stopped
4 selling; right?

5 MR. SNELL: Form, predicate.

6 A. Yes.

7 Q. (By Mr. De La Cerda) Gynemesh they
8 changed the indication; right?

9 A. That's -- yeah, I became aware of that.

10 Q. And that avoided Ethicon having to comply
11 with the studies required in the 522 orders; correct?

12 MR. SNELL: Objection, speculation.

13 A. I don't agree with that --

14 Q. (By Mr. De La Cerda) Why not?

15 A. -- last statement. Because I'm not -- I'm
16 disagreeing on the basis that there's -- they could
17 not continue without doing the 5- -- the 522s. I
18 think that a fair trial of this would have been to at
19 least be on the committee that the FDA had. And there
20 was actually the voice of surgeons saying these are --
21 this is the evidence and part of the evidence was
22 presented on a communication. It was signed by over
23 400 surgeons and still that was ignored.

24 And that has less to do with what Ethicon

1 could do, the way I look at it, the way I appreciate
2 it, and more to the fact that the FDA decided no, this
3 is the way it's going to be, 522s or -- or not. So
4 what could they do?

5 Q. This is an interesting point that's come up
6 in my mind. Why is it that the physicians didn't
7 petition Ethicon to comply with the 522 orders? If
8 the product was so good, why don't the physicians say,
9 "Hey, Ethicon, this stuff is great, do the 522 orders,
10 we know it's going to turn out great, we all win"?

11 Why was there no petition for Ethicon to do
12 that?

13 MR. SNELL: Calls for speculation.

14 A. I -- I don't know. That's exactly -- I'm
15 going to -- I'm going to probably answer it that way
16 because it calls for speculation.

17 Q. (By Mr. De La Cerda) Ultimately, if the
18 product's great, why didn't Ethicon do the studies?

19 Have you ever been provided a rationale as
20 to why Ethicon decided not to do the 522 studies?

21 A. No, there was no -- no rationale and we
22 still cannot find a rationale for that, for not
23 complying with the 522. I think that you can -- you
24 cannot tell a company how they're going to go about

1 their -- running their business. Although I would
2 like, yeah, to have that power to tell everyone to run
3 their business, it's not like I'm going to be listened
4 on that. And there are other considerations that they
5 may have.

6 I can tell you that from a surgeons'
7 perspective, yeah, we could have been compelled --
8 going along the statement that you just made, we could
9 have been compelled to go to Ethicon and I think that
10 that was conveyed at some point, but there's no -- no
11 way to go about it when you're imposed a 522 just off
12 like that.

13 And I think that part of it -- just to
14 elab- -- elaborate on that -- part of it was that we
15 saw -- we signed that petition, we signed that letter,
16 we say, "Please reconsider this. Let's find another
17 method to do this. There has to be a better method to
18 do this." And I think ten years from now we're going
19 to look back on this and we're going to say that was
20 an inadequate method. It was too rigid and we have to
21 find other methods to have these devices available to
22 surgeons.

23 Q. Is it necessarily a bad thing, though, for
24 clinical studies to be required before another

1 transvaginal pelvic organ prolapse mesh is put on the
2 market? I mean, is that a bad thing? Isn't that a
3 good thing because it can ensure safety for patients?

4 MR. SNELL: Form.

5 A. I could -- let me tell you, I'm -- by now,
6 you know that I have done research in one way or
7 another for 25 years and I sponsor individuals to do
8 research and I believe in research and I believe in
9 evidence.

10 I can -- I will never be able to say, "Oh,
11 no, we don't need another study." I think that
12 everybody wants another study, but the fact is that
13 are we going to put individuals through a study when
14 we have evidence from -- from before, multiple
15 randomized control trials, how fair is that to do
16 another study with women when we have evidence of how
17 it works?

18 Q. (By Mr. De La Cerda) Do you know if any
19 of the hospitals that you have privileges at had any
20 Prolift or Prosima devices leftover after Ethicon
21 stopped selling those products?

22 A. No, that's -- in my -- my hospital, there
23 was -- it was not there. Basically the communication
24 came in and the communication is clear and that was

1 it.

2 Q. What do you mean by the "communication"?
3 Did Ethicon say, "Hey, take it off your shelves"?

4 A. No, we have a product manager in the
5 operating room and any of us that have -- any surgeon
6 that receives a letter would go and send it right away
7 to the product manager.

8 Q. And what did the letter say?

9 A. That's the decommercialization letter.

10 Q. Okay.

11 A. And that was it.

12 Q. And so at the time it was decommercialized
13 did those products then get pulled from the shelves of
14 the hospital?

15 A. Yeah, that's it, they're in a separate cart
16 and the cart doesn't work anymore. I actually tried
17 to find one a few -- a few months later, I couldn't
18 find it. No, that goes to a facility, gets destroyed,
19 that's it.

20 Q. Okay. Here's a few statements, I want to
21 see if you agree with them.

22 Do you agree serious complications
23 associated with surgical mesh for transvaginal repair
24 of pelvic organ prolapse are not rare?

1 A. They are rare.

2 Q. They are rare?

3 A. They are rare.

4 Q. So you disagree with that statement?

5 A. I disagree with the statement that they are
6 not rare.

7 Q. Do you agree that there is no evidence that
8 transvaginal repair with mesh provides any added
9 benefit compared to traditional surgery without mesh?

10 A. That's inaccurate and it's not supported by
11 evidence.

12 Q. So you disagree with that one?

13 A. I do.

14 Q. Do you agree that it's not clear that
15 transvaginal repair with mesh is more effective than
16 traditional non-mesh repair in all patients with
17 pelvic organ prolapse and it may expose patients to
18 greater risk? Do you agree or disagree with that?

19 A. I disagree with that.

20 Q. Do you agree that mesh used in transvaginal
21 pelvic organ prolapse repair introduces risks not
22 present in traditional non-mesh surgery for pelvic
23 organ prolapse repair?

24 A. I -- in a general sense, I disagree with

1 that except with a fact that the risk is inherent to
2 the implant only.

3 Q. Which would be exposure; right?

4 A. Which would be mesh exposure.

5 Q. Mesh exposure. Mesh exposure.

6 Okay. Do you agree mesh placed abdominally
7 for a pelvic organ prolapse repair results in lower
8 rates of mesh complications compared to transvaginal
9 pelvic organ prolapse surgery with mesh?

10 A. I don't agree -- I don't agree with that.
11 And the basis for my disagreement with it isn't only
12 the clinical -- the clinical evidence, but also my
13 experience.

14 Q. Do you agree that native tissue repairs have
15 similar outcomes to synthetic mesh without the risks
16 inherent in mesh use?

17 MR. SNELL: Form, vague.

18 A. They -- the evidence shows in randomized
19 control trials that native tissue repairs have
20 other -- other risks.

21 Q. (By Mr. De La Cerda) So you would
22 disagree with this statement; right?

23 A. Yes, I would.

24 Q. Do you agree or disagree the native

1 tissue -- strike that.

2 Do you believe it would be a reasonable
3 decision for a doctor to stop using the Prosima device
4 following the July, 2011, FDA warning?

5 MR. SNELL: Incomplete hypothetical,
6 speculation.

7 A. I think that there's a -- I mean, I will
8 have to think for all the other surgeons, but I think
9 it's reasonable whenever you have a letter from an
10 organization like the FDA and you -- all of us not
11 being completely -- completely aware of that process
12 on how it came through, it comes as a surprise that we
13 don't have a problem. I think it comes as a surprise
14 not only for us, it comes as a surprise for the
15 patients.

16 Q. (By Mr. De La Cerda) So it would be
17 reasonable for a doctor to do that?

18 A. I think it's reasonable for anyone to think
19 that there's something wrong and it requires a lot of
20 reading and a lot of research to really be in tune
21 with the reality.

22 Q. And so it would also be reasonable for a
23 doctor to stop using the Prolift and the Gynemesh
24 transvaginally after that July, 2011, FDA warning;

1 correct?

2 MR. SNELL: Same objection, speculation,
3 incomplete hypothetical.

4 A. It's a -- it's reasonable on the basis of
5 human nature.

6 Q. (By Mr. De La Cerda) At any point after
7 the July, 2011, FDA warning, did you decide to stop
8 using Prosima, Prolift or Gynemesh transvaginally?

9 A. I think that everyone look at it and
10 everyone stop using it for the wrong reasons, less
11 because of evidence, and more because of the -- of the
12 fear of being involved in litigation, which is real,
13 and being involved in a situation having to explain
14 themselves when there is not a clear -- a clear
15 picture about the reality of it.

16 Q. But you did stop using Prosima, Prolift and
17 Gynemesh transvaginally at some point after the July,
18 2011, FDA warning; right?

19 A. I -- I think I continue using what -- what
20 it did, it did happen is that I communicated, "Listen,
21 we need to take a look at this," but I continued using
22 it.

23 Q. You continued implanting it?

24 A. Yes.

1 Q. Until they were pulled from the market or
2 stopped, they were stopped selling or
3 decommercialized; right?

4 A. Yes, once you have -- you have that, I
5 don't -- I don't want to use it.

6 Q. Do you agree -- do you agree that surgical
7 mesh to repair pelvic organ prolapse is a high-risk
8 device?

9 A. It's a --

10 MR. SNELL: Foundation.

11 Go ahead.

12 A. It's a game like talking about 522, some
13 510(k)s, high risk, low risk, it's not -- it's not
14 scientifically accurate.

15 I do agree that if you're going -- if you're
16 going to use it, you need to be well-trained on it,
17 and you just don't start doing prolapse or continence
18 procedures because a device is easy to use. You still
19 have to be trained and read what's behind all that.
20 That's my opinion of how I run my professional career.
21 It's my -- my profession.

22 That's how we do it on credentialing in my
23 hospital, that's going to be up to the credentialing
24 institutions and the physicians to decide how much

1 training they will -- they will have.

2 Q. (By Mr. De La Cerda) And so at this
3 point, you can't tell me whether you can label
4 surgical mesh to repair pelvic organ prolapse as
5 high risk; right?

6 A. Yeah, it's labeled high risk and there's
7 communication from the FDA labeling it high risk.
8 What I -- I can tell you is that the terminology of
9 high risk or low risk brings other implications. If
10 you look at the evidence, I will say, "Well, you know,
11 it's really a risky procedure like any surgery."

12 Q. And so you're not going to offer testimony
13 that the Gynemesh implanted transvaginally or the
14 Prosima or Prolift are low-risk devices, are you?

15 MR. SNELL: Objection, misstates his prior
16 testimony.

17 Go ahead.

18 A. I will not go with low risk or high risk. I
19 think that whole terminology is so -- is so
20 nonspecific. What's -- if I -- if you compare it to a
21 heart surgery, if you compare it to -- to any other --
22 an appendectomy, there's always risk. So I cannot
23 classify one way or the other.

24 There's -- there's -- I believe that there

1 is more to that high-risk, low-risk classification
2 than what we can actually explain on the frame of a
3 deposition.

4 Q. (By Mr. De La Cerda) Do you know whether
5 or not Ethicon did an internal risks analysis to
6 determine risk scores for the pelvic organ prolapse
7 mesh devices? Like whether they were going to --
8 whether Ethicon was going to label them low,
9 moderate, high risk?

10 A. I'm not aware of them doing that and
11 actually, there's -- there was an effort, not by
12 Ethicon but by the professional societies to use the
13 Dindo classification and modify it for -- for
14 prolapse. So that's -- that tells you the extent.

15 The reason why I'm explaining is it tells
16 you the extent of how elaborate the process is. I
17 don't think that Ethicon probably -- I think they were
18 too busy with other things to develop anything,
19 anything like that.

20 Q. Let's switch gears a little bit here.

21 Are you okay on breaks?

22 A. I'm good.

23 Q. Okay. We are getting close. Okay.

24 If a synthetic graft product like Prosima

1 does not do better than a native tissue repair in
2 terms of safety and efficacy, do you think it should
3 be introduced to the market?

4 MR. SNELL: Foundation.

5 Go ahead.

6 A. The -- the basis for Prosima for any other
7 procedure, they don't do well with whatever benchmark
8 that you use, you need to reconsider, you need -- you
9 have a choice in the market, obviously, but there's --
10 that's not what we saw with Prosima. The cohort
11 studies done on Prosima follow the experience with
12 Prolift and it showed that it was better than native
13 tissue repairs.

14 Q. (By Mr. De La Cerda) You're aware that
15 Ethicon was told by some of its top consultants it
16 did not make sense to use the Prosima in people with
17 lesser degrees of prolapse given the outcomes?

18 A. Any consultant may have an opinion. That's
19 something that -- that's something that Ethicon always
20 foster for anyone to give an opinion. And it's not
21 like we were that shy of giving an opinion because we
22 actually offer plenty of it.

23 Q. Would you disagree with that -- this
24 particular opinion?

1 A. I disagree.

2 Q. Do you agree or disagree with the following
3 statement: There is no authoritative paper to support
4 that Prosima outcomes are superior or even comparable
5 to colporrhaphy?

6 A. I disagree with that, and the papers are
7 authoritative and within the context of evidence
8 previously gathered by the use of Gynemesh and
9 Prolift.

10 Q. So if the primary investigator for the
11 Proxima trial which studied whether or not the product
12 was effective for Grade II and III rectocele and
13 cystoceles made that statement, you would disagree
14 with her?

15 A. I'm not aware -- are you speaking about
16 Dr. Zyczynski?

17 Q. I guess ultimately -- you know, what I'll
18 do, I'll just withdraw the question. I think you've
19 already answered anyway.

20 You disagree with the prior statement, so I
21 think you answered that anyway.

22 A. I'm going to refer to her on first name
23 because I think that she will be okay with it. Her
24 first name is Halina, H-a-l-i-n-a.

1 Q. If the overall consensus of a medical device
2 company's consultants and experts is that it would be
3 a mistake to launch a device on the market, do you
4 think it would be wrongful for the company to launch
5 that device anyway?

6 A. The --

7 MR. SNELL: Wait. Hold on. Objection,
8 speculation, incomplete hypothetical.

9 A. The fact that you are a scientist doesn't
10 always mean that you're going to know marketing.
11 That's -- there's more than one person making those
12 decisions.

13 Q. (By Mr. De La Cerda) So you don't believe
14 that it would necessarily be wrongful for a company
15 to launch a product under those circumstances; is
16 that right?

17 MR. SNELL: Same objection.

18 A. I think there's more than one opinion that
19 needs to be considered, especially in a multicenter
20 study.

21 Q. If the overall consensus of a medical device
22 company's scientists and experts is that it would be a
23 mistake to launch the device on to a market, do you
24 think that doctors or patients who are provided the

1 device should be told the company's scientists and
2 experts think that the device is a mistake?

3 MR. SNELL: Form, foundation, incomplete
4 hypothetical.

5 A. Yeah, I don't think that any company is
6 going to tell you, "Yeah, I'm going to release it and
7 it's mistake."

8 No, the evidence is there and -- and the
9 evidence was so very clear with Prosima. It was
10 presented in modules, it was presented on the number
11 of patients, it was presented in a multicenter study.
12 It had all the qualities of a good cohort study.

13 Q. (By Mr. De La Cerda) So you don't think
14 that a doctor or -- a doctor who's implanting a
15 Prosima or a patient who's going to receive a
16 Prosima wants to know before that Prosima is put in
17 that at some point the top consultants and experts
18 at the company believe that Prosima was a mistake,
19 they believe it was a reckless product, that they
20 believe if they put the product out on the market
21 they were going to stop working with Ethicon, you
22 don't think any of that information should be
23 provided to doctors or patients?

24 A. No.

1 MR. SNELL: Hold on. You've got to give me
2 a chance.

3 Form, foundation.

4 Go ahead.

5 A. No, it's -- I don't think that's -- that
6 that should be considered. I think that the
7 scientific evidence supersedes whoever feels that it's
8 in so much power to say, "Oh, it's reckless because I
9 say it's reckless."

10 Well, this is the evidence, this is the
11 scientific evidence, this is the multicenter evidence.
12 If you insist on calling it reckless or giving an
13 irresponsible opinion, which is what it is, then it's
14 up to you, but this is the evidence on this device.

15 Q. (By Mr. De La Cerda) So Marcus Carey, you
16 know, is the inventor of Prosima; right?

17 A. Yes.

18 Q. And you know he received -- he would receive
19 royalties each time the Prosima was sold; right?

20 MR. SNELL: Foundation.

21 A. I -- I'm aware that he got paid for his
22 work.

23 Q. (By Mr. De La Cerda) Do you know how much
24 he got paid?

1 A. No.

2 Q. Do you know he was the lead author on the
3 Prosima study done by Ethicon prior to launch?

4 A. There was the first one and then there was
5 another study.

6 Q. Do you know what his success rate was with
7 the Prosima in that first study?

8 A. It's -- on the -- the first study was
9 around -- above the hymenal ring, I believe it was in
10 the '70s.

11 Q. What about below? Below the -- I just lost
12 the word. Hymenian, is that what you said?

13 A. Hymenal ring.

14 Q. Hymenal ring.

15 MR. SNELL: Let me caution you. If you have
16 a study, you should pull it out and look at it.
17 He's not asking you to guess. I mean, we have
18 all this stuff here, you can look at it.

19 THE WITNESS: Okay.

20 MR. SNELL: I don't know where you have it,
21 but I would assume it's in one of these things.

22 A. This is it. This is the study.

23 Q. (By Mr. De La Cerda) Okay. So go back to
24 the question. Do you know what his success rate was

1 with the Prosima in his first study?

2 A. Let me look through it and I'll --
3 73.9 percent.

4 Q. And you say that is above or below the
5 hymenal ring?

6 A. That's about the hymenal ring.

7 Q. And how about below the hymenal ring?

8 A. The rest of it.

9 Q. What do you mean "the rest of it"?

10 A. The other percentage.

11 Q. So it's 70/30?

12 A. Yes, it's 70 -- yes, it's 73.9 versus
13 20-something. Either one, yeah.

14 Q. Do you think the fact that he was the
15 inventor of the product introduced bias in that study?

16 THE WITNESS: Let me point out -- do you
17 see -- you saw that, right?

18 MR. SNELL: Okay.

19 A. Please repeat the question.

20 Q. Sure.

21 Do you think the fact that he was the
22 inventor of the Prosima introduced bias into that
23 study?

24 A. No.

1 Q. Why not?

2 A. I have no reason to believe that he would be
3 bias with it.

4 Q. Do you know whether Ethicon thought there
5 was a fair amount of spin going on regarding Dr. Carey
6 reporting of his clinical data?

7 A. Fair amount of?

8 Q. Spin. Have you ever heard that term "spin,"
9 spinning the data, spinning the information?

10 A. No, no.

11 Q. Like the politicians do?

12 A. I have no reason to believe that
13 Professor Carey had any deviations from what he would
14 honestly do.

15 Q. Do you know whether Ethicon believed that
16 Dr. Carey was spinning the data?

17 A. No. No, I don't -- I'm not aware of that.

18 Q. The inventor of Prolift, Dr. Cosson,
19 C-o-s-s-o-n --

20 A. Cosson.

21 Q. Cosson.

22 MR. SNELL: Misstates, lacks foundation.
23 You've got the wrong person.

24 Q (By Mr. De La Cerda) Is he the inventor of

1 Prolift?

2 A. It was a group.

3 Q. It was a group, right.

4 A. It was a group.

5 Q. You've relied on -- have you relied on data
6 and literature published by Dr. Cosson and the TVM
7 group to support your conclusions that Prolift is safe
8 and effective?

9 MR. SNELL: Same objection.

10 A. Well, there was a TVM and there was Prolift.
11 And TVM was a precursor, but is different from the
12 product on Prolift.

13 Q (By Mr. De La Cerda) Okay. Do you know if
14 Dr. Cosson receives royalties for the Prolift or
15 received?

16 A. No, I don't -- I'm not aware of what he
17 received.

18 Q. Do you believe that an inventor who receives
19 royalties for selling his invention can be potentially
20 biased when publishing data regarding his invention?

21 MR. SNELL: Speculation.

22 A. I don't -- I don't see them being biased. I
23 have no reason to believe that would be the case.

24 Q. (By Mr. De La Cerda) You're very

1 trusting. You're very trusting.

2 A. This is high caliber -- high-caliber
3 investigators.

4 Q. Well paid, too.

5 You're aware that Ethicon had an alternative
6 mesh to Gynemesh PS that they believe would cause
7 fewer compli- -- fewer serious complications at least
8 as early as 2006; right?

9 MR. SNELL: Foundation, misstates the
10 evidence.

11 A. Could you please repeat that?

12 Q. (By Mr. De La Cerda) Sure.

13 Are you aware that Ethicon had an
14 alternative mesh to Gynemesh PS that they believed
15 would cause fewer complications at least as early as
16 2006?

17 MR. SNELL: Same objections.

18 A. No, I'm not aware of that, any mesh like
19 that, but I'm also aware that there's very low
20 likelihood that there was any evidence strong enough
21 for Prolene polypropylene.

22 Q. (By Mr. De La Cerda) What do you mean by
23 that?

24 A. The evidence on Prolene polypropylene, on

1 the behavior of the material, it's -- it was
2 well-established by the time Gynemesh PS came in.

3 Q. So you don't believe it's possible that
4 Ethicon can have evidence that it had a mesh different
5 from Gynemesh that they believe was safer than
6 Gynemesh?

7 MR. SNELL: Objection, same objection.

8 A. I believe it's possible to have another
9 mesh. What I don't believe is that the mesh could be
10 based to be safer or with more evidence.

11 Q. (By Mr. De La Cerda) Okay. I'm going to
12 ask you whether you agree with the following
13 statements.

14 Do you agree that physicians should be
15 aware -- made aware of all of the significant safety
16 risks associated with the product in the IFU?

17 MR. SNELL: Objection, asked and answered.

18 I think he's testified three times on this.

19 A. The -- the risk of the IFU should pertain to
20 the device. There is no place in the IFU to make a
21 more comprehensive guide for incontinence, nor should
22 the IFU replace training, expertise and textbook
23 reading.

24 Q. (By Mr. De La Cerda) But you agree that

1 all significant safety risks associated with the
2 product should be included; right?

3 MR. SNELL: Objection, misleads prior
4 testimony.

5 Go ahead.

6 A. With the -- with the product specifically
7 associated to the device and -- and -- and the mesh.

8 Q. (By Mr. De La Cerda) Is that a "yes"?

9 MR. SNELL: Objection, asked and answered.

10 A. To the device and mesh, yes.

11 Q. (By Mr. De La Cerda) Okay. Do you agree
12 that a manufacturer of a medical device that would
13 be implanted in a woman's body is required --
14 actually, strike that.

15 Do you agree that an IFU should never
16 exclude known hazards or complications?

17 MR. SNELL: Objection, I think this is all
18 asked and answered. He's given the same opinions
19 numerous times.

20 Go ahead.

21 A. The IFU should talk about the things that
22 are inherent to the device. It's -- it's a guide
23 about the device.

24 Q. (By Mr. De La Cerda) Can't -- is it okay

1 for it to exclude known hazards or complications?

2 MR. SNELL: Form.

3 Q. (By Mr. De La Cerda) There are
4 circumstances where I think you believe that it can
5 exclude known hazards and complications; right?

6 MR. SNELL: Same objections.

7 A. Things that are not at risk to the patient.

8 Q. (By Mr. De La Cerda) No, I mean -- okay.

9 If it's a known hazard or complication to it
10 that could happen to a patient, should it ever be
11 excluded from an IFU?

12 MR. SNELL: Same objection.

13 A. If it's -- if the complication or the side
14 effect is the same as it would happen with a native
15 tissue repair, I believe that it does not have to be
16 included on the IFU.

17 Q. (By Mr. De La Cerda) Okay. Do native
18 tissue repairs result in chronic foreign body
19 reaction?

20 A. Yes.

21 Q. How is that?

22 A. There's a reaction to sutures. There's the
23 plication of tissue that dehisce. There is the
24 formation of hematomas or granulomas. There are the

1 inherent conditions of the host that could cause it,
2 such as atrophy, autoimmune disorders, lichen planus.
3 So there are a number of conditions that can make a
4 native tissue repair not work, not work well or have
5 granulation tissue or have chronic -- chronic
6 inflammation.

7 Q. Chronic inflammation. Okay.

8 Do you agree that if a patient undergoes the
9 TVT procedure under general anesthetic, it has the
10 potential to put the patient at increased risk for
11 urinary retention or urethral erosion?

12 A. No.

13 Q. And why is that?

14 A. Initially, the idea was that when you put a
15 midurethral sling, which is tension free, that you
16 have to adjust it so the patient would not be on
17 retention.

18 It was -- it was later described that that
19 may have been true for previous slings that were used
20 ideally for vesical junction, but not for midurethral
21 slings. Eventually, the data proved that to be
22 correct, because the rate of voiding dysfunction was
23 below 1 percent.

24 So one of the -- one of the things that that

1 experience validated is something that they didn't
2 know, not even the inventor actually knew that, which
3 is that there is some viscoelasticity to the implant
4 itself.

5 MR. DE LA CERDA: Okay. What I'd like to do
6 now is take a break and review my notes and
7 then --

8 MR. SNELL: I'm ready for another bathroom
9 break.

10 MR. DE LA CERDA: We'll go off the record,
11 thank you.

12 (Thereupon, a recess was taken from
13 3:24 p.m. until 3:45 p.m., after which the
14 following proceedings were held:)

15 Q. (By Mr. De La Cerda) Okay. Doctor, we're
16 back on the record.

17 There was one thing you mentioned that I
18 wanted to make sure was clear. When we were talking
19 about the compensation you had received as a
20 consultant and then we had a discussion about trying
21 to get --

22 MR. SNELL: I haven't gotten that either.

23 MR. DE LA CERDA: That's fine. That's fine.
24 Get a better version.

1 MR. SNELL: People are running around like
2 on your side, too, like all over the place.

3 Q. (By Mr. De La Cerda) There was a
4 discussion about trying to get -- there's a
5 spreadsheet that has listed out some of this
6 information and you mentioned, "Well, it might only
7 be money that was allocated for me, but not
8 necessarily money that I made."

9 Do you remember discussing that? You might
10 not have used the term --

11 A. Yes.

12 Q. -- "allocated."

13 A. Yes, they did their own allocations for what
14 they were going to spend. It was a budget, internal
15 thing from Ethicon, a budget planning. So it could --
16 my point is that it could say a number -- it would
17 never be higher than that number, but it was -- it
18 could be lower than that.

19 Q. So the numbers in the spreadsheet may just
20 be what would have been an allocation or a budget for
21 you for that year and it couldn't be higher, but it
22 might be lower?

23 A. But it might be lower, yes. It cannot be
24 over that number.

1 Q. Okay. Okay. And then have you had a chance
2 to review that on your own, that spreadsheet?

3 A. I saw it before -- before the Cavness trial
4 and I saw it at the Cavness trial.

5 Q. And are you sure one way or the other
6 whether those numbers are allocated versus real
7 numbers?

8 A. They're -- I know they're not real numbers
9 because I would have -- I would have remembered that.

10 Q. Yeah.

11 A. The number is -- is high, and I don't
12 remember having 1099s that were that high.

13 Q. Okay. Okay. Have you understood all of my
14 questions today?

15 A. Yes, sir.

16 Q. Have you answered them truthfully and to the
17 best of your ability?

18 A. Absolutely.

19 Q. Is there any testimony that you would like
20 to go back and change at this point?

21 A. No.

22 MR. DE LA CERDA: Okay. I'll pass the
23 witness.

24

1 CROSS-EXAMINATION

2 BY MR. SNELL:

3 Q. Doctor, I want to go through some topics and
4 I'm actually going to go in the order that
5 Mr. de la Cerda covered things just to make sure we're
6 all clear on the record here about where you intend to
7 testify and the bases and whatnot.

8 Do you recall at the beginning of the
9 deposition you were asked by Mr. de la Cerda about
10 that Abbott study where some of the patients didn't
11 return back to the implanting surgeon for care of a
12 complication?

13 A. Yes.

14 Q. All right. In formulating your opinions on
15 the devices we've been discussing today, are there
16 studies in databases that have captive audiences that
17 look at treatment over time regardless of whether it's
18 the implanter, explanter, or someone else?

19 A. No, there's -- one of the -- one of the
20 things that we have with these type of procedures is
21 that there have been tracks on Medicare databases,
22 they -- and we have other -- other -- other databases
23 that I -- and the citations I put, the Kaiser
24 Permanente, that's --

1 Q. Why don't we go there because that's what I
2 was going to ask you about. If you turn to page 14
3 and 15 --

4 A. Yes, I got it.

5 Q. -- of your TVT, TVT-O report. Do you
6 identify different database studies that assess
7 reoperation complication management regardless of who
8 actually is doing that surgery?

9 A. Right.

10 Q. Okay.

11 A. The Canadian registry, there is Medicare,
12 and there's Kaiser Permanente.

13 Q. So -- and did you find those studies to be
14 reliable?

15 A. That is -- that is reliable.

16 Q. So let's take the first one that I'm looking
17 at, it's reference No. 45 in your report, Jonsson
18 Funk, J-o-n-s-s-o-n, Funk. It's the nine-year study
19 where the rate of removal for mesh urethrolysis was
20 3.7 percent.

21 A. Yes.

22 Q. Do you have a recollection as to whether
23 that study contained, you know, over a 100,000
24 patients or --

1 A. There was -- I know for a fact it's over
2 80,000 patients, close to -- close to 100,000
3 patients. Most importantly, that rate of -- of
4 revision was about 3 percent.

5 Q. And did you see a similar rate as to about
6 3 percent in different database studies and other
7 studies like the Cochrane reviews and randomized
8 control trials?

9 A. Consistently you go from one paper to
10 another to another and it's 3 percent. It's 2 percent
11 on one, 3 percent. The maximum I have seen is
12 5 percent. But the number that is most consistently
13 repeated is 3 percent. And that's -- that's accurate
14 to cite to the patients.

15 Q. So in the Abbott study, let me ask you this.
16 Do you recall that it was a case series based on
17 tertiary referral centers by Dr. Karram, who I think
18 plaintiff's counsel mentioned, and a couple other
19 doctors?

20 A. Yes, there are probably two papers that say
21 patients would not follow through. The first one is
22 about the -- a review about randomized control trials
23 or any follow up in which patients do not show up,
24 they tend to be considered as -- in the group that did

1 not respond to therapy, to treatment, or to the
2 intervention.

3 The second is that paper that you just
4 mentioned, but the overwhelming data is so high in
5 other areas, in other databases that we don't go by
6 specific papers like that.

7 Q. So the case series, can -- when you
8 formulated your opinions, did you pay attention and
9 put more effort -- more emphasis on higher level data?

10 A. Not only formulate my opinions. In
11 everything I read, I need -- I need to know what is it
12 that I'm reading. And I put that scale, that bridge,
13 some people see it as a pyramid, some people see it as
14 a list. We know that case series are at the bottom,
15 randomized control trials reviews are on the top.

16 Q. The first study, the Jonsson Funk study, can
17 you identify, just for the record, how many patients
18 did that involve in the assessment?

19 A. It's 188,454 eligible women.

20 Q. And then the other footnotes, 46, 47, 48,
21 and 49, were those also the different databases you
22 mentioned?

23 A. Right. The Canadian, the Canadian also has
24 good reliability because the Canadian does have -- has

1 a tracking because of their socialized system. They
2 have tracking. They are known to be able to track a
3 variety of conditions, and this is just another one
4 that they -- that they are -- they report.

5 Q. And so I guess my question is: Did you find
6 these database studies from different databases, based
7 on the volume of patients assessed and the
8 methodologies, to be more reliable than a case series
9 in a limited number of patients?

10 A. Absolutely, besides these are up in the
11 hierarchy.

12 Q. You were asked some questions about what you
13 did in formulating your opinions and you've talked
14 about and testified that you reviewed the medical
15 literature. I want to make sure we're clear here.

16 Did you also look at various Ethicon company
17 documents and evaluate them?

18 A. Yes, I -- I -- I did. I just -- in the
19 order -- in the order that I read them, I -- I read
20 them most remotely. In other words, I -- it has been
21 more time since I read than from this.

22 Q. Did you specifically identify in your report
23 Ethicon documents on topics that Mr. de la Cerda asked
24 you about, like mechanical cut versus laser cut, and

1 degradation and pore size and things like that in your
2 reports?

3 A. Well, by -- through the -- through my
4 testimony today, I address. There is no way I would
5 have been able to address it if I wouldn't have read
6 it.

7 Q. I think you testified to this and you can
8 tell me if I'm correct or wrong.

9 Did you earlier testify that based on all of
10 your analyses and the bases you talked about here
11 today, that you have not identified any
12 characteristics of the mesh that are a safety risk?

13 A. Yeah, I don't -- I don't think that there
14 are concerns about safety on -- on -- on any of the
15 products that we were using. If I would have thought
16 there were concerns about safety to begin with, I
17 wouldn't have used them.

18 Q. And besides the medical literature and the
19 high-level data that you have referenced, do you also
20 rely on your clinical experience?

21 A. There's -- my experience is important, the
22 data is important, and the caliber of the data is
23 important. Not only that, my experience and the
24 experience of the people that I -- that I talk to.

1 You see, it's -- in medicine, we still -- we
2 still value very much the experience, the experience
3 of our colleagues, so I use that and I use also the
4 experience of -- my own experience and the experience
5 of those that investigate. People -- people that are
6 extremely talented are looking at studies.

7 Q. And at the end, though, in formulating your
8 opinions and coming to your final conclusions about
9 the safety and efficacy of Gynemesh PS, Prolift, TVT,
10 TVT-O, did you put more weight into the randomized
11 level on control trials than individual experience or
12 case series?

13 A. Randomized control trial is what -- what we
14 wish we would have on everything. But once you have a
15 few randomized control trials, you can build up with
16 other -- with the other studies. You cannot just do
17 the reverse, you have to build up on the strongest
18 ones.

19 Q. You were asked a lot of questions about your
20 opinions on IFUs and you told Mr. de la Cerda various
21 grounds and bases for your opinions and you talked
22 about how you had reviewed IFUs over many years and
23 numerous times.

24 Let me ask you this. In your professional

1 education role, did you teach and cover the IFU with
2 other pelvic surgeons specific to these devices we
3 talked about today?

4 A. We could -- we could make -- the answer is
5 yes. We could make any presentation and present any
6 slide, but at the end when we're working together in
7 the specimen and they collaborate, it's the IFU, the
8 one that comes out.

9 And as a -- as a preceptor or as a teacher,
10 you need to know that IFU by -- by steps and know not
11 only what it says, but what it really says in terms of
12 mechanics. That's important for all -- all products.

13 Q. And how many of the cadaver labs or these
14 labs that you did included covering the IFU with the
15 surgeons?

16 A. Every single -- every single lab.

17 Q. How many cadaver labs did you do on these
18 products? Your best estimate is fine.

19 A. The VCS here did about six cadaver labs
20 locally. We had -- we used to go to Orlando and it
21 was very convenient for me because when I would miss
22 the plane, because I was seeing patients, I would just
23 drive up there, and it's -- and it was six in the max
24 year, maybe eight.

1 Q. Would there be just one surgeon at this
2 event or would there be multiple?

3 A. No, multiple surgeons. There was more than
4 one -- one preceptor.

5 Q. Do you have an estimate as to the number of
6 pelvic floor surgeons you would have worked with and
7 trained and went through the IFU with?

8 A. I never -- never saw more than four. And if
9 I will have two, that would be good. We -- we started
10 with the IFU. We would teach the device and after
11 that, one of the opportunities that we have in the
12 cadaver lab is that we could dissect and get an
13 in-depth view of what -- where the devices went by
14 using the IFU. So it was the ultimate test for an IFU
15 and the test is on performance of the procedure.

16 Q. You were asked questions about TVT and these
17 products and you expressed the opinion that you don't
18 think that the devices rope, curl, degrade, et cetera.

19 Did you -- so let me -- so with that
20 preface, did you look at the literature to see whether
21 any of the studies in the patients reported a
22 difference or a hypothesis as to a difference as to
23 laser cut versus mechanical cut mesh? Are there any
24 studies that describe it?

1 A. There is not -- there are no actual studies
2 that define one way or the other.

3 There is actually the well-designed
4 randomized control trials, like the TOMUS, which is
5 evaluating midurethral sling, transobturator and
6 retropubic. And what -- in that specific study, which
7 is an excellent study, it's one of the pillars of what
8 we do, it's -- we -- we found out there was no
9 description of one or the other; and I have the
10 impression that both were used and there was never any
11 difference on it.

12 Q. For the mechanical versus laser cut, do you
13 cover that in-depth in your report on pages 23 through
14 25?

15 A. Yes.

16 Q. Do you have -- is there a TVT-Secur report
17 over there?

18 A. Yeah.

19 Q. Do you recall a study by the name -- maybe
20 the first author's name was Neuman that looked at
21 TVT-O versus TVT-Secur and it reported percentages of
22 complications for erosion and dyspareunia and there
23 was a difference seen on dyspareunia which the authors
24 reported may have been to -- may have been due to

1 laser cut mesh. Do you recollect that?

2 A. That's Dr. Menahem Neuman's study. He's in
3 Israel and he study -- he studied TVT-Secur.

4 Q. What page are you on?

5 A. That's 44.

6 Q. And was that the only study that you were --
7 that you found in your investigation in the clinical
8 application of these products on women that suggested
9 there may be a difference between the two?

10 A. There's a -- there's another -- another
11 study that Bianchi-Ferraro and on the -- both of them,
12 there are TVT-Os and TVT-Securs compared and there's
13 no difference on them. That's -- this is just -- this
14 is just illustrate that mechanical cut and laser cut,
15 unless you put it on extreme conditions, way beyond
16 the stressors that would be found on the pelvis, there
17 is no significant difference on the behavior.

18 Q. Page 45 on the Neuman study, you wrote that
19 the authors theorized that the laser cut mesh was to
20 blame for higher dyspareunia, but there is no
21 scientific data confirming that.

22 A. There is no scientific data and that is just
23 an opinion and that's -- that's what we -- we have to
24 define what's science, what's an opinion. Sometimes

1 you see a study that has good science, but then it
2 becomes an opinion at the end.

3 Q. Do you recall Mr. De al Cerda asking you
4 about a hypothetical that if laser cut mesh was three
5 times stiffer or more stiffer than mechanical cut mesh
6 would it lead to more complications and he may have
7 even mentioned exposure. Do you recall?

8 A. Yeah, I do recall.

9 Q. My question to you is: So in that study by
10 Neuman, did the laser cut mesh have a significantly
11 different rate of erosion than the mechanical cut
12 mesh?

13 A. There's -- the rate of erosions were -- was
14 lower on the Secur. It was zero versus a 1.4 on the
15 TVT-O.

16 Q. Have you found any reliable, convincing
17 clinical study evidence that, in your mind,
18 establishes that there is a significant difference in
19 laser and mechanical cut mesh when implanted with the
20 TVT devices in women?

21 A. There has been no study up to now and,
22 obviously, I'm giving you the opinion that I will
23 welcome any study that makes a difference between --
24 between the two of them.

1 The Cochrane database, actually, did not
2 define that. There is no other study that has defined
3 it.

4 Q. Do you have an opinion as to whether the
5 weight, pore size, and width of the TVT mesh is proper
6 in that device for the treatment of stress urinary
7 incontinence?

8 A. For which device specifically?

9 Q. For the TVT, TVT-O devices, do you believe
10 that the mesh is the proper weight, pore size, and
11 width?

12 A. Yes, and that's -- that's -- that's a mesh
13 that has the evidence behind it.

14 Q. And when you say "the evidence," are you
15 talking about the various evidence that you put into
16 your reports?

17 A. Yeah, we have come to the point, even the
18 communication from the FDA, most recent one, just --
19 just speaks about the standard for continence care
20 being a midurethral sling.

21 Q. You were asked a question by plaintiff's
22 counsel about the lighter weight mesh and larger pore
23 mesh.

24 Has any lighter weight or larger pore mesh

1 been studied as much or demonstrated to be as useful
2 and safe as the mesh in TVT for the application of
3 stress incontinence?

4 A. For -- for stress incontinence specifically,
5 there is no other mesh that has been tested to the
6 extent -- actually, there's no other continence
7 procedure material that have been tested to the extent
8 of TVT.

9 Q. And is that all different types of studies
10 or just randomized control trials?

11 A. There are all types of studies that -- but
12 predominantly randomized control trials as -- and
13 we're talking about devices for urinary incontinence.

14 Q. You were asked a lot of questions about
15 degradation. Do you believe that the available data
16 shows that the Prolene mesh degrades?

17 A. No.

18 MR. DE LA CERDA: Form.

19 Q. (By Mr. Snell) And did you review
20 specifically studies referenced by plaintiff's
21 counsel and others, you went and looked for like the
22 Clavé paper, that purportedly raised this issue of
23 degradation?

24 A. That is one descriptive paper in which we --

1 we can actually look at 26 samples of low density.
2 That's 26 samples out of close to over 2 million --
3 between 2 million and 3 million slings that I don't
4 think you can reliably give any opinion on that and
5 actually, if it would degrade, I would expect it to
6 perform worse, and that's not the evidence that we
7 have.

8 Q. Is there evidence, long-term data, that
9 shows sustained durability and low complications in
10 your view?

11 A. Yes. There is data at five years, ten years
12 and now I believe there is data bordering on the 15
13 years.

14 Q. And is that data, in your opinion,
15 consistent or inconsistent with the degradation
16 theory?

17 A. No.

18 Q. What's that?

19 A. It's not consistent with the degradation
20 theory. It's actually inconsistent.

21 Q. In the Clavé study, did you see that besides
22 the fact that a minority of the mesh is -- had this
23 surface cracking on SEM, when they actually did the
24 chemical analytical testing, did those tests

1 demonstrate degradation?

2 A. No, the samples -- the samples were poorly
3 treated to the point that they -- they were not given
4 a good for analysis.

5 Classically, explant -- explanted tissue --
6 I'm sorry, explanted graft is not a good -- it's not a
7 good sample to begin with, much less when you put it
8 through -- through spectroscopy, spectroscopy or
9 chromatography and much less through thermal --
10 thermal changes.

11 Q. Were there -- in the Clavé paper, did you
12 see that the authors acknowledged that there was no
13 control group to compare?

14 A. No, that's not a control -- control study.
15 That's barely a descriptive study.

16 Q. Did you find any of the data that purported
17 to raise this issue of the hypothesis degradation to
18 be reliable?

19 A. No, I have not seen one yet that proves
20 degradation with any definition that I've been given
21 of degradation.

22 Q. Mr. de la Cerda asked you about cytotoxicity
23 and your report -- your report, I believe, covers that
24 pretty much in-depth.

1 A. Yes.

2 Q. And you talked with Mr. de la Cerda about
3 the various Ethicon documents and testing you've
4 reviewed and your opinion about the different types
5 and what those studies show or don't show.

6 A. Yes, I -- I reviewed the -- Ethicon actually
7 ask a third-party lab to do it. It's a third-party
8 lab in Germany and the reports are clear on all the
9 assays.

10 Q. And I think Mr. de la Cerda asked you to
11 identify, you know, the bases for your opinion for
12 your cytotoxicity opinions and you identified those
13 documents in your analysis.

14 Let me ask you this. Is the basis for your
15 cytotoxicity opinions also your personal experience on
16 assessing cytotoxicity issues?

17 MR. DE LA CERDA: Leading.

18 A. Yeah, well, I assess cytotoxicity with word
19 in science starting to see cytotoxicity in -- in 1985,
20 from 1985 to 1986, that's all I did in the lab. And
21 it's -- I did that -- I actually presented it at a
22 conference on -- on pharmaco -- on molecular
23 pharmacology. And that's -- that's my experience with
24 it.

1 Q. (By Mr. Snell) So you have personal
2 experience in cytotoxicity analyses?

3 A. I have done bench -- I have done bench work
4 on cytotoxicity.

5 Q. Did you also evaluate the clinical
6 literature on these devices to see whether they
7 documented or raised a phenomenon that you would
8 attribute to cytotoxicity?

9 A. I went through all these documents and I
10 read the results on each one of them and I -- I'm in a
11 good position to see what -- what the assays show.

12 Q. In your opinion, is the TVT mesh cytotoxic?

13 A. No.

14 Q. You were asked about clinical data that was
15 available before TVT-O -- the TVT-O device was
16 marketed. Do you recall just covering that topic with
17 Mr. de la Cerda?

18 A. Yes.

19 Q. Was there data on -- clinical data, clinical
20 studies on the TVT device before TVT-O went to market?

21 A. There was clinical data, yes.

22 Q. Is that data relevant, in your opinion, to
23 TVT-O?

24 A. Yes, it is.

1 Q. Is it the same mesh?

2 A. It's the same implant.

3 Q. You were asked about the MSDS sheet that you
4 looked at for the raw polypropylene and a statement in
5 it to the effect that the raw polypropylene -- I don't
6 remember the specific, but it had something to do with
7 compatibility.

8 My question to you is this: Is the TVT
9 compatible with the female human body implanted --
10 implantation in the pelvis for treatment of stress
11 incontinence?

12 A. It is biocompatible. It has been
13 demonstrated that it's biocompatible and it has no
14 similarity to raw polypropylene.

15 Q. That was going to be my next question. Is
16 raw polypropylene implanted in the TVT process -- TVT
17 device?

18 A. It's a -- it's a different thing. Totally
19 different -- different type of material.

20 Q. There was a discussion about sarcoma
21 formation in rats when raw polypropylene was implanted
22 in disk or powder form. Do you recall that?

23 A. Yes.

24 Q. Is TVT disk or powder form?

1 A. No. And TVT has not been as to a sarcoma
2 and there is actual -- actually a publication about
3 it.

4 Q. I think in your report at page 26 you go
5 through some of the different epidemiologic studies
6 with regard to the polypropylene slings and cancer and
7 sarcoma.

8 A. On the --

9 Q. On the --

10 A. Which one of the reports?

11 Q. Probably be TVT, TVT-O report, page 26.

12 A. Yes.

13 Q. The top paragraph where you state: "The
14 available data does not show any causal links between
15 polypropylene and cancer," and then you have numerous
16 footnote citations.

17 A. Actually, the evidence is for lack of the
18 carcinogenic.

19 Q. And as part of Exhibit 11 there is a paper
20 by the lead author Linder where there was over 2,000
21 midurethral sling patients who were analyzed. I'll
22 just hand it to you. We'll make sure we put it back
23 into Exhibit 11.

24 A. Yes.

1 Q. Is that one of the studies that form the
2 basis of your opinion that the data show
3 noncarcinogenic --

4 A. The rate of cancer in these patients was
5 reported to be below baseline.

6 Q. Have you seen any studies utilizing the
7 Prolene polypropylene in any of these devices we
8 discussed today that show a statistically significant
9 elevated risk of sarcoma formation or cancer in women
10 over and above the expected background rate?

11 A. No.

12 Q. And in that study by Linder you just
13 mentioned, is it correct that 49 of the 50 patients
14 had cancer already a baseline?

15 A. Yeah, that's -- that's the only -- it's 2
16 out of 2,474. That's what makes for .0- -- 08.
17 That's extremely low. That's actually lower than the
18 reported -- one of the cases was an ovarian cancer and
19 that's lower than the reported rate of ovarian cancer.

20 Q. Let me put that back in Exhibit 11. Make
21 sure we don't lose that.

22 You were asked questions by Mr. de la
23 Cerde -- I'm going to circle back around to the
24 lighter weight, larger pore mesh theory.

1 Do you know whether actually the TVM group
2 evaluated a larger pore, lighter weight mesh in the
3 development of what became Prolift --

4 MR. DE LA CERDA: Leading.

5 Q. (By Mr. Snell) -- that was besides
6 Gynemesh PS?

7 A. They did. They did and it's in my Reliance
8 List. Professor Jack Tanny evaluated the IFUs of
9 different meshes with absorbable components and with
10 large pore size. Their first conclusion and that's
11 non- -- the first conclusion wasn't Dr. -- Professor
12 Berrocal, B-e-r-r-o-c-a-l.

13 Professor Berrocal's paper in which the
14 statement was clear the TVM group decided that no
15 absorbable meshes were going to be used. And when a
16 combination was used without a partial absorbable
17 partial polypropylene, they decided that the pore size
18 being so large did not work.

19 Q. Did you see whether or not the surgeons
20 evaluating the different meshes also evaluated a mesh
21 called Vipro?

22 A. They did. That's exactly what they did.

23 Q. Is that a large pore, lightweight mesh as
24 well?

1 A. Yeah, it's a large -- large pore. You can
2 get pores as high as 5-, 6,000 microns.

3 Q. Did that mesh demonstrate better efficacy or
4 tolerability than the Gynemesh PS?

5 A. No, actually it was -- the performance was
6 worse.

7 Q. You've heard of the mesh Ultrapro,
8 obviously. Mr. de la Cerda talked to you today about
9 presentations concerning the potential benefits of
10 lighter weight or larger pore meshes.

11 A. Yes.

12 Q. Does the Ultrapro mesh also have a risk of
13 mesh exposure?

14 A. We had -- when we say "we," as the surgeons
15 doing these procedures, we expected that it was going
16 to be less mesh exposure. We actually found that it
17 was exactly the same.

18 Q. And same thing for dyspareunia or pain?

19 A. Yes.

20 Q. In your Prolift report -- do you have that
21 handy? Let's go to page 10 and 11.

22 A. Yes.

23 Q. Before we actually get to that, let me ask
24 you this.

1 Did you see any clinical studies that you
2 found to be reliable that showed that a larger pore or
3 lighter weight mesh than Gynemesh PS was more
4 effective or safer than Gynemesh PS in the Prolift,
5 Prosima or Prolapse application?

6 A. No, it was -- it remained on a hypothesis.
7 It remained just as a hypothesis and just we -- we all
8 consider at one point that when we we're talking, I'm
9 talking again about the surgeons, the word preceptors
10 and the other surgeons, which one is going to have the
11 longest data behind it and it was polypropylene.

12 Q. You mentioned earlier, told Mr. de la Cerda,
13 based on your review of the most reliable data that
14 actually the Gynemesh PS and Prolift had a lower risk
15 of wound complications in native tissue. Do you
16 recall that?

17 A. Yes.

18 Q. And I think you also testified that based on
19 your analysis, there was a lower rate or risk of
20 vaginal stenosis requiring surgery for the Gynemesh PS
21 compared to native tissue and you mentioned the Carey
22 study?

23 A. That is correct. That's accurate.

24 Q. Was that the same Carey study we were

1 looking at earlier?

2 A. Yes.

3 Q. Do you know where that is? I want to ask
4 you a question about it.

5 A. That is in the --

6 Q. My question is: Do you have it over there
7 somewhere? I just want to ask you a question about
8 it.

9 Oh, here it is.

10 A. It is the paper before the last one on the
11 top to the left.

12 Q. So page 1384, does that report and what you
13 referenced in that randomized control trial that there
14 was a higher rate of reoperation for vaginal stenosis
15 in native tissue compared to the mesh?

16 A. That's correct.

17 Q. Do you remember Mr. de la Cerda asked you
18 did Ethicon ever test the pliability of the mesh?

19 A. Yes, I do recall that.

20 Q. Now, pliability of the mesh, I think you
21 told Mr. de la Cerda, that that could be related to
22 stenosis or pain.

23 A. Well, it's -- one thing is that the
24 pliability and the other thing is about the

1 contraction or shrinkage and what we were talking was
2 along the lines of what mesh contraction or mesh can
3 increase the pliability. Pliability of a tissue or
4 the elasticity of the tissue has more to do with the
5 tissue itself.

6 Now, the question is, if the mesh could add
7 to this and the answer is every clinical indication of
8 shrinkage or -- or elasticity does not hold the test
9 of clinical evaluation. If there would be a
10 shrinkage, there would be an actual contraction. The
11 vagina would be shorter. And there is no -- there's
12 no study that demonstrates that the vagina is shorter
13 on this -- on all patients that have been repaired
14 with mesh.

15 We have had instances in which the vagina is
16 shorter with native tissue repair because there's no
17 augmentation with the mesh. So -- and that
18 communication is not just on my opinion, that's part
19 of the communication that was sent to the FDA.

20 Q. Are you talking about the paper that was
21 endorsed by hundreds of pelvic surgeons?

22 A. Yes.

23 Q. At page 10 and 11 of your report you talk
24 about the Cochrane review and then the randomized

1 control data do not show a statistically significant
2 difference in de novo dyspareunia, de novo pelvic
3 pain, vaginal pain, change in sexual function, or
4 change in vaginal length or vaginal caliber.

5 A. That's the latest Cochrane review, that's
6 exactly what it demonstrates.

7 Q. And did you also assess the randomized
8 control trials to see if that was an accurate
9 statement, specifically for Gynemesh PS and Prolift?

10 A. Yeah, there's a -- there's an actual --
11 there's a -- there are randomized control trials and
12 there is the Lowman paper in which mesh is placed
13 transabdominally, sacrospinously on fixations,
14 uterosacral suspensions, anterior/posterior repairs,
15 they were all evaluated for the incidence of
16 dyspareunia.

17 Q. You mention that the urine analysis was
18 consistent with the findings by Dietz and Maher, who
19 did a systematic review and found no difference in
20 post-operative or de novo dyspareunia or change in
21 sexual function. Do you see that?

22 A. Yes.

23 Q. And that citation is number 24?

24 A. 24.

1 Q. Is that a high-level of evidence, a
2 systematic review metanalysis?

3 A. That is at the highest level.

4 Q. And is that what your opinions are based
5 upon?

6 A. Yes.

7 Q. You were asked questions by Mr. de la Cerda
8 about characterization of mesh as high risk or low
9 risk, and I think you basically disagreed and said you
10 prefer to kind of evaluate it on its own terms. Is
11 that correct or not?

12 A. I -- I saw the classification of low risk or
13 high risk to be restrictive and the question is if
14 this -- if this procedure is done with mesh have a
15 higher risk over native tissue repairs.

16 Q. Did he -- I'm sorry, go ahead.

17 A. And the answer to that is every time we look
18 at that randomized control trial, the answer to that
19 is no.

20 Q. So my question is this: Have you put in
21 your report and will you be prepared to discuss at
22 trial how Prolift, Prosima, Gynemesh PS comparing
23 risk, whether it's less risky or higher risk than
24 native tissue repair for things that we talked about

1 today with Mr. de la Cerda like recurrence, wound
2 complications, pain, change in vaginal shape, length,
3 things like that?

4 MR. DE LA CERDA: Form.

5 A. Surgery has risk. Surgery has multiple
6 risk. Surgery for prolapse has specialized risk that
7 we face every single time that we work with mesh or
8 without mesh. We haven't had a mesh now for a few
9 years and patients still having the same kind of
10 complications that they had with the exception of a
11 mesh exposure because there's no mesh.

12 Incisions still dehisce the same way,
13 incisions still separate, challenges of wound healing
14 are still seen, granulation tissue is still seen, and
15 actually what we're seeing now is a higher rate of
16 hysterectomies with -- with shorter vaginas.

17 Q. (By Mr. Snell) Do you plan to discuss at
18 trial how the rates and risks with the Gynemesh PS,
19 Prolift, Prosima compare to the rates and risks with
20 native tissue?

21 MR. DE LA CERDA: Form.

22 A. Yes.

23 Q. (By Mr. Snell) For example, in your
24 report, you -- so for your Prolift report, page 9,

1 you have -- you have multiple studies that show the
2 efficacy of Prolift and Gynemesh PS compared to
3 native tissue. Do you see that?

4 A. Yes.

5 Q. Do you plan to talk about the different
6 rates and risks of recurrence for mesh-based repair,
7 particularly I'm focused on Ethicon Gynemesh PS and
8 Prolift, Prosima compared to native tissue.

9 MR. DE LA CERDA: Form.

10 A. Yes.

11 Q. (By Mr. Snell) And do you plan to discuss
12 rates of wound complications, sexual function and
13 dyspareunia for Ethicon's meshes compared to native
14 tissue?

15 MR. DE LA CERDA: Form.

16 A. Yes, I plan -- I plan to testify on those.

17 Q. (By Mr. Snell) And have you evaluated and
18 investigated those issues?

19 A. I have thoroughly evaluated. I have -- I
20 run randomized control trial after randomized control
21 trial. I have highlighted the areas that I feel are
22 most important and I have summarized them today on
23 my -- on my testimony.

24 Q. And have you also identified those --

1 examples of those data in your reports, as well?

2 A. I am -- I am ready to go on presented on the
3 numbers.

4 Q. Lastly, Mr. de la Cerda asked you about if
5 you had any plans for further work in the formulation
6 or analysis. Obviously, you're being deposed today
7 and tomorrow and I will represent to you that there
8 are transcripts not yet available for plaintiffs'
9 experts and some of plaintiffs' experts are not being
10 deposed until even after you.

11 Do you plan to review those transcripts when
12 they're provided to you and assess them?

13 A. I will -- I will evaluate them. I'll assess
14 them, and I'm looking forward to see the scientific
15 validity of it.

16 MR. SNELL: Okay. That's all I have.

17 MR. DE LA CERDA: Nothing further from me.

18 MR. SNELL: Thank you.

19 THE COURT REPORTER: Do either of you need a
20 rough draft on this?

21 MR. SPARKS: Yeah, I put my email on --

22 MR. DE LA CERDA: Yeah, I'll take one, too.

23 (Thereupon, the taking of the deposition
24 was concluded at 4:33 p.m.)

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CERTIFICATE OF OATH

STATE OF FLORIDA)
COUNTY OF BROWARD)

I, JODY L. WARREN, Registered Professional
Reporter, Florida Professional Reporter, Notary
Public in and for the State of Florida at Large,
certify that the witness, JAIME SEPULVEDA, M.D.,
personally appeared before me on 3/30/16 and was
duly sworn by me.

DATED this 11th day of April, 2016.

JODY L. WARREN, RPR, FPR
Notary Public, State of Florida at Large
My Commission Expires 2/28/19
My Commission No. FF 188650

CERTIFICATE OF REPORTER

I, JODY L. WARREN, Registered Professional Reporter, Florida Professional Reporter, certify that I was authorized to and did stenographically report the deposition of JAIME SEPULVEDA, M.D., the witness herein on 3/30/16; that a review of the transcript was requested; that the foregoing pages are a true and complete record of my stenographic notes of the deposition by said witness.

I further certify that I am not a relative, employee, attorney, or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

DATED this 11th day of April, 2016.

JODY L. WARREN, RPR, FPR

Notary Public, State of Florida at Large

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I, _____, do

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hereby certify that I have read the

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foregoing pages, and that the same is

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a correct transcription of the answers

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JAIME SEPULVEDA, M.D.

DATE

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Subscribed and sworn

to before me this

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_____ day of _____, 20____.

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My commission expires: _____

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Notary Public

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